南方科技大学医学伦理委员会（SUSTech IRB）

初始审查申请表

一、项目概况	
项目全称	可粘附电极-皮肤离电传感结构
经费来源	广东省基础与应用基础研究基金
项目负责人	郭传飞
项目负责人单位	南方科技大学
项目负责人 E-mail	guocf@sustech.edu.cn
项目负责人电话/手机	18124682257
项目协调人	黄涛
项目协调人 E-mail	huangt@sustech.edu.cn
项目协调人电话/手机	13564852741
二、经费来源	
√中国政府 口美国联邦政府 口基金会 口院、校课题 口研究生课题 口企业 口其他：深圳市科委	
资助方名称（资助编号）	2021A1515110862
三、研究者利益冲突	
请确认课题负责人、主要参加者、课题其他主要人员（或其直系亲属等）是否存在以下情形之一： • 与项目申办方或研究将要使用的药物、器械或技术存在经济或知识上的利益，或从中获得报酬？ • 是研究中所采用的药物、器械或技术的发明人或专利持有人？ • 与本研究之间已经存在或者预计在一年内将发生财务上的关系（例如，咨询、演讲、担任顾问、专利、股权和期权，等） □ 是，**请填写并提交“经济利益声明表”** √否	

四、研究团队主要成员（请根据实际情况增加表格）					
姓名	学历	专业/职称	隶属机构	承担角色	近两年是否参加过伦理培训
黄涛	博士	材料科学与工程/研究助理	南方科技大学	项目协调人	是

		教授			
郭传飞	博士	材料科学与工程/教授	南方科技大学	项目负责人	是

五、该研究是否是多中心研究？

☐ 是；请填写下表其他中心概况（可根据实际情况增加表格）

√ 否，请直接填写第六部分

研究中心名称	联系人/电话	该研究中心内是否有伦理委员会？	如果**有**伦理委员会，请选择：
		☐有 ☐无	☐ 该伦理委员会将对该项目进行审查 ☐ 该伦理委员会将接受本伦理委员会的审查决定

六、研究摘要（请逐项填写，若某项不涉及，填写“无”）

研究设计 (可多选)	√病例对照研究 ☐队列研究 ☐横断面研究 ☐非随机对照研究 ☐随机对照研究 ☐应用盲法 ☐其他：
研究目的	本实验开发了一种用于触觉增强的电刺激贴片,需要研究评估该类贴片在触觉障碍患者应用效果。
受试者选择 （包括入排标准）	处于触觉障碍中人群，包含糖尿病患者、周遭神经损伤患者等
对照设置	触觉健康人群。
干预措施	无
主要观察指标	1. 人体触觉阈值； 2. 人体对位点的感知识别度
随访情况	无
样本量	5 人以内
统计分析	对患者的触觉阈值与位点识别准确率进行统计分析
风险判断	☑不大于最小风险 ☐大于最小风险
研究可能涉及的风险包括：	皮肤过敏性发红、电刺激带来的疼痛感。
风险控制措施包括： （请具体描述）	若发生过敏症状：撕去贴片、擦拭去过敏药膏； 若发生电刺激痛感：降低电流刺激强度。
研究获益属于	☐ 直接获益； √ 间接获益； ☐ 两者都有

研究可能的获益是：（请具体描述）	对项目制备的皮肤贴片适用人群起到决定作用，为后续该贴片的进一步发展、文章发表以及相关项目申请起到积极租用		
数据安全监管计划（隐私保护、数据安全等质量保障措施等，请具体描述）	所获得数据仅包含受试者局部皮肤状态照片，该数据将不会暴露受试者的身份信息，数据安全性较高		
计划研究时间	2024 年 1 月 5 日 至 2024 年 2 月 1 日		
七、受试者招募、知情同意、费用和补偿			
谁负责招募（可多选）	√ 项目负责人 √ 研究者 □ 医生 □ 护士 □ 其他：_____		
招募方式（可多选）	□ 招募启事 √ 互联网 □ 电子邮件 √ 微信 □ 手机短信 □其他（请注明）：____		
计划招募地点（请填写具体场所，如门诊、病房等）	南方科技大学专家公寓		
是否使用招募材料	√否 □是 →请作为送审文件一并提交		
谁进行知情同意（可多选）	√ 项目负责人 √ 研究者 □ 医生 □ 护士 □ 其他：_____		
知情同意形式	□ 纸版知情同意 □ 口头知情同意 √ 电子知情同意 □ 不适用（拟申请免除知情同意）		
知情同意是否涉及代理同意	□ 是，请明确： □ 监护人/法定代理人； □ 其他（请注明）：_____ √ 否		
知情同意过程质量控制措施（请具体描述）	当面告知所进行实验内容，告知所可能出现的症状，请被告之人了解实验内容过程，在第三方人员在场下进行知情过程签署		
知情同意文档管理计划	对知情同意书进行整理归档保存		
与研究有关的医疗检查与治疗	√免费 □部分免费 □不免费 □不适用		
参加研究相关交通、餐补等	500 元/例 □ 无	其他补偿	_____ 元/例 □ 无

八、特殊审查要求	
☐	申请免除知情同意过程
☐	申请免除签署书面知情同意文件
☐	申请开展在紧急情况下无法获得知情同意的研究
☐	研究涉及弱势群体 →请明确： ☐儿童/未成年人 ☐服刑人员 ☐孕妇 ☐认知障碍或因健康状况而没有能力做出知情同意的成年人 ☐申办者/研究者的雇员或学生 ☐教育/经济地位低下的人员 ☐疾病终末期患者 ☐其他（请注明）：_____ 注：弱势群体是个相对概念。多指儿童、孕妇、胎儿、新生儿（不能存活或存活能力未知）、存在认知障碍的成年人、医学上不能够做出知情同意的成年人、由于语言不通存在交流障碍的人、老年人（>90 岁）、受教育程度低下/存在经济困难的人群、疾病终末期患者（预期寿命<3 个月），等。
☐	研究涉及侵入性检查、放射性检查
☐	研究涉及纯属研究目的且在常规医疗/体检之外进行生物标本采集
☐	研究涉及人类遗传资源的采集和保藏（人类遗传资源是指含有人体基因组、基因及其产物的器官、组织、细胞、核酸制品等资源材料及其产生的信息资料）。 重要提示：请咨询南方科技大学科研部，提交相关材料（电话：18565858818）。
☐	研究涉及干细胞
九、送审文件（另附，参见附件“送审文件清单”）	
十、项目负责人声明：	
我确保该表格所有填写内容以及所有送审文件的真实性。 **我声明将遵循国际公认伦理准则、国内相关法规以及南方科技大学医学伦理委员会相关要求，开展本项研究。** 项目负责人签字：_____黄涛_____； 日期：____2024-1-4_____	

申报单位意见		单位盖章	
主管领导签字		日期	年 月 日

附件：送审文件清单（请勾选所提交文件并填写版本信息）：

		文件名称
√	1	项目负责人专业履历
√	2	项目负责人伦理培训证明
√	3	研究方案
√	4	知情同意书
□	5	研究病历和/或病例报告表
□	6	受试者日记卡
□	7	调查问卷
□	8	招募受试者的材料（包括广告等）
□	9	曾向其他机构伦理委员会提交申请的相关说明（附审查材料、审查决定文件）

注：1-3 项为必须提交，其余文件根据项目具体情况提交。

IRB of the Southern University of Science and Technology

Initial review application chart

1.General situation	
Project tile	Adhesive Electrode for Iontronic Sensing Structure
Funding source	Guangdong Provincial Fund for Basic and Applied Basic Research
Principal investigator	Chuanfei Guo
Institution of PI	Southern University of Science and Technology
E-mail of PI	guocf@sustech.edu.cn
Contact Information	18124682257
Contacts	Tao Huang
E-mail of Contacts	huangt@sustech.edu.cn
Contact Information	13564852741
2. Funding Source Information	
√ Chinese government ☐ the United States Federal Government ☐ Foundation ☐ School project ☐ Postgraduate research project ☐ Enterprise ☐ Others	
Grant number	2021A1515110862
3. Researcher Conflict of Interest	

Please confirm whether the project leader, key participants, or other key personnel (or their immediate family members, etc.) have any of the following circumstances:

- Do they have any economic or intellectual interests, or receive any compensation from the project sponsor or from the drugs, devices, or technologies to be used in the research?
- Are they the inventor or patent holder of the drugs, devices, or technologies used in the study?
- Do they have, or are they expected to have within one year, any financial relationships with this research (e.g., consulting, speaking engagements, acting as an advisor, patents, equity, stock options, etc.)?

☐ Yes, Please complete and submit the "Statement of conflict of Interests" form.

√ No.

4. Key members of the research team (please add to the table as necessary based on the

actual situation).					
Name	**Education**	**Specialization/ Title**	**Affiliated Institution**	**Role in the Project**	**Has the individual participated in ethics training in the past two years?**
Chuanfei Guo	Ph.D.	Material science and engineering/ Professor	Southern University of Science and Technology	PI	Yes
Tao Huang	Ph.D.	Material science and engineering/ Research Assistant Professor	Southern University of Science and Technology	Project Collaborator	Yes

5.Is this research a multi-center study?

□ Yes; please fill in the table below with details of other centers (additional tables can be added as necessary).

√ No, fill the part 6 directly.

Research Center Name	**Contact Person/Phone Number**	**Does this research center have an Ethics Committee?**	**If there is an Ethics Committee, please select:**
		□Yes □No	□ The Ethics Committee will review this project. □ The Ethics Committee will accept the review decision of this Ethics Committee.

6. Research Summary (Please fill in each item. If a particular item is not applicable, write "N/A")

Research Design (You may select multiple options)	√Case-Control Study □ Cohort Study □Cross-Sectional Study□Non-Randomized Controlled Study □Randomized Controlled Study □Blinded Method Applied □Other:

Purpose of research	This project has developed an electrical stimulation patch for tactile enhancement, and the study aims to evaluate the effectiveness of this patches in patients with tactile impairments.
Subject Selection (Including inclusion and exclusion criteria)	Inclusion criteria: (1) This study will primarily select participants with tactile impairments resulting from diabetes, stroke, neurological diseases, or physical injuries. Participants should generally exhibit symptoms of tactile dysfunction or limb numbness. (2) The study will also invite individuals with normal tactile sensation as a control group. Exclusion Criteria: (1) Participants with severe skin lesions, including extensive skin ulceration or trauma, will be excluded. (2) Individuals with severe allergic conditions will also be excluded from the study.
Control Group	Healthy individuals with normal tactile function.
Intervention	None
Primary indicators	1. Current/weight threshold； 2. Location/shape recognition；
Follow-up situation	None
Sample size	Within 5 samples
Statistical Analysis	P-value statistical analysis was performed on the data.
Risk Assessment	☑ Not greater than minimal risk □ Greater than minimal risk
Potential risks involved in the study include:	- Skin allergic reactions such as redness. - Pain caused by electrical stimulation.
Risk mitigation measures include: (Please provide specific details)	- In case of allergic symptoms: remove the patch and apply anti-allergy ointment. - In case of pain from electrical stimulation: reduce the current intensity.
Research benefits	□ Direct benefits； √ Indirect benefits； □ Both
Possible benefits of the research:	The research will help determine the target population for the skin patch developed in the project, contributing to the further development of the patch, publication of related articles, and future project applications.
Data security oversight plan	The data collected will only include photographs of the local skin condition of the subjects, and this data will not expose the subjects'

(including privacy protection, data security, and other quality assurance measures, please describe specifically):	personal identity information. The security of the data is therefore high.
Planned Research Duration	5th, Jan., 2024 to 1st, Feb., 2024
7. Subject Recruitment, Informed Consent, Costs, and Compensation	
Who is responsible for recruitment (You may select multiple options)	√ Principal Investigator √ Researcher □ Doctor □ Nurse □ Others：_____
Recruitment Methods (You may select multiple options)	☐ Recruitment notices √ Internet □ E-mail √ WECHAT ☐ SMS □ Others：____
Planned Recruitment Location (Please specify the exact locations, such as outpatient clinics, wards, etc.)	Southern University of Science and Technology Expert Apartments
Will recruitment materials be used?	√No □Yes → Please submit them as part of the approval documents.
Who will obtain informed consent (You may select multiple options)	√ Principal Investigator √ Researcher □ Doctor □ Nurse □ Other：_____
Informed Consent Form	√Paper-based informed consent □Verbal informed consent □Electronic informed consent□Not applicable (exemption requested from informed consent
Does informed consent involve proxy consent?	□ Yes, please specify: □ Guardian/Legal Representative； □ Others：_____ √ No
Quality control	The study details and potential symptoms are explained in person to

measures for the informed consent process (please describe specifically):	the participant. The participant is fully informed of the procedure, and the informed consent is signed in the presence of a third party to ensure transparency.		
Informed Consent Document Management Plan	The informed consent forms will be organized, archived, and securely stored.		
Medical examinations and treatments related to the study	√Free □Partially free □Not free □Not applicable		
Transportation, Meals, and Other Study-Related Compensation	500 Yuan/sample □ None	Other Compensation	_____ Yuan/sample √ None

8. Special Review Requirements	
□	Application for Exemption from the Informed Consent Process
□	Application for exemption from signing written informed consent forms
□	Application to conduct research where informed consent cannot be obtained in emergency situations
□	Research Involves Vulnerable Populations → Please specify: □Children/Minors □Incarcerated individuals □Pregnant women □Adults with cognitive impairments or those unable to provide informed consent due to health conditions □Employees or students of the sponsor/researchers □Individuals with low educational or economic status □End-of-life patients □Other (please specify):_____ Note: Vulnerable populations is a relative concept, generally referring to children, pregnant women, fetuses, newborns (unable to survive or with unknown survival potential), adults with cognitive impairments, adults who are medically incapable of providing informed consent, individuals with communication barriers (e.g., due to language differences), elderly individuals (>90 years old), those with low educational levels or economic hardship, end-of-life patients (life expectancy < 3 months), etc.
□	Research involves invasive procedures or radiological examinations
□	Research involves the collection of biological samples for purely research

	purposes, outside of routine medical exams or checkups
□	Research involves the collection and preservation of human genetic resources (human genetic resources refer to materials such as organs, tissues, cells, nucleic acid products, etc., that contain human genomic information, genes, and their products, as well as the data generated from them). Important Notice: Please consult the Research Department of Southern University of Science and Technology and submit the relevant materials (Phone: 18565858818).
□	Research involves stem cells
9. Submission Documents for Review (See attached documents)	
10. Statement of the Principal Investigator:	

I ensure the accuracy and truthfulness of all the information provided in this form and all submission documents.

I declare that I will conduct this research in accordance with internationally recognized ethical guidelines, relevant domestic regulations, and the requirements of the Southern University of Science and Technology Medical Ethics Committee.

Principal Investigator：___ Chuanfei Guo ___； Data：____2024-1-4____

Opinion of the Applicant Institution		Institutional Stamp	
Signature of the Supervising Leader		Data	

Attachments: Submission Document Checklist

(Please check the submitted documents and provide version information):

		Document Name
√	1	Principal Investigator's Professional Resume (Signature, Signing Date)
√	2	Principal Investigator's Ethics Training Certificate
√	3	Research Protocol
√	4	Informed Consent Form
□	5	Research Medical Records and/or Case Report Forms
□	6	Subject Diary Cards

□	7	Survey Questionnaire
□	8	Recruitment Materials (including advertisements, etc.)
□	9	Explanation of previous submissions to other Ethics Committees (including review materials, review decision documents)

Note: Items 1-3 are required to be submitted, and other documents should be submitted based on the specifics of the project.

南方科技大学医学伦理审查表决书

决议编号	20240005
项目名称	可粘附电极-皮肤离电传感结构
受理编号	2024PES005
申请时间	2024 年 1 月 4 日
是否通过初审	□**通过**√ □**不通过**
会议或通讯审查的时间	2024 年 1 月 10 日
伦理审查结果	□**通过** √ □**修改再审查** □**不通过**
伦理委员会审批意见： 同意，立项后由医学伦理委员会审查监管。 2024 年 1 月 11 日	

IRB of the Southern University of Science and Technology

Review Voting Document

Decision serial number	20240005
Project's title	Adhesive Electrode for Iontronic Sensing Structure
Acceptance serial number	2024PES005
Time of application	4th, January, 2024
If it passed the first review	☐Approve✓ ☐Disapprove
Data of meeting and review	10th, January, 2024
Ethical review results	☐Approve✓ ☐Re-examination after modification. ☐Disapprove
Decision committed by ethics committee: Approved, the project complies with scientific and technological ethics standards.	

南方科技大学医学伦理委员会（SUSTech IRB）

初始审查申请表

一、项目概况	
项目全称	基于皮肤-电极界面的压力传感研究
经费来源	国自然科学基金
项目负责人	郭传飞
项目负责人单位	南方科技大学
项目负责人 E-mail	guocf@sustech.edu.cn
项目负责人电话/手机	18124682257
项目协调人	黄涛
项目协调人 E-mail	huangt@sustech.edu.cn
项目协调人电话/手机	13564852741
二、经费来源	
√中国政府 口美国联邦政府 口基金会 口院、校课题 口研究生课题 口企业 口其他：	
资助方名称（资助编号）	52073138
三、研究者利益冲突	
请确认课题负责人、主要参加者、课题其他主要人员（或其直系亲属等）是否存在以下情形之一： • 与项目申办方或研究将要使用的药物、器械或技术存在经济或知识上的利益，或从中获得报酬？ • 是研究中所采用的药物、器械或技术的发明人或专利持有人？ • 与本研究之间已经存在或者预计在一年内将发生财务上的关系（例如，咨询、演讲、担任顾问、专利、股权和期权，等） □ 是，**请填写并提交“经济利益声明表”** √否	

四、研究团队主要成员（请根据实际情况增加表格）					
姓名	学历	专业/职称	隶属机构	承担角色	近两年是否参加过伦理培训
郭传飞	博士	材料科学/教授	南方科技大学	项目负责人	是

黄涛	博士	材料物理化学/研究助理教授	南方科技大学	项目协调人	是
黄毅	博士	心内科/医师	南方科技大学医院	项目合作者	是

五、该研究是否是多中心研究？

√ 是；请填写下表其他中心概况（可根据实际情况增加表格）

☐ 否，请直接填写第六部分

研究中心名称	联系人/电话	该研究中心内是否有伦理委员会？	如果**有**伦理委员会，请选择：
南方科技大学医院	黄毅/13670029152	√有 ☐无	☐ 该伦理委员会将对该项目进行审查 √ 该伦理委员会将接受本伦理委员会的审查决定

六、研究摘要（请逐项填写，若某项不涉及，填写“无”）

研究设计 (可多选)	√病例对照研究 ☐队列研究 ☐横断面研究 ☐非随机对照研究 √随机对照研究 √应用盲法 ☐其他：
研究目的	本项目开发了一种用于触觉增强的电刺激贴片，需要研究评估该类贴片在触觉障碍患者应用效果。
受试者选择 （包括入排标准）	处于触觉障碍中人群，包含糖尿病患者、周遭神经损伤患者等
对照设置	触觉健康人群。
干预措施	无
主要观察指标	1. 人体触觉阈值； 2. 人体对位点的感知识别度； 3. 其他感觉，如温度的模拟感知
随访情况	无
样本量	50 人以内
统计分析	对患者的触觉阈值与位点识别准确率进行统计分析
风险判断	☑不大于最小风险 ☐大于最小风险
研究可能涉及的风险包括：	皮肤过敏性发红、电刺激带来的疼痛感。
风险控制措施包括：	若发生过敏症状：撕去贴片、擦拭去过敏药膏；

（请具体描述）	若发生电刺激痛感：降低电流刺激强度。		
研究获益属于	☐ 直接获益； √ 间接获益； ☐ 两者都有		
研究可能的获益是： （请具体描述）	对项目制备的皮肤贴片适用人群起到决定作用，为后续该贴片的进一步发展、文章发表以及相关项目申请起到积极租用		
数据安全监管计划（隐私保护、数据安全等质量保障措施等，请具体描述）	所获得数据仅包含受试者局部皮肤状态照片，该数据将不会暴露受试者的身份信息，数据安全性较高		
计划研究时间	2024 年 6 月 27 日 至 2024 年 8 月 1 日		
七、受试者招募、知情同意、费用和补偿			
谁负责招募（可多选）	√ 项目负责人 √ 研究者 √ 医生 ☐ 护士 ☐ 其他：_____		
招募方式（可多选）	☐ 招募启事 √ 互联网 ☐ 电子邮件 √ 微信 ☐ 手机短信 ☐其他（请注明）：____		
计划招募地点（请填写具体场所，如门诊、病房等）	南方科技大学医院门诊		
是否使用招募材料	√否 ☐是 →请作为送审文件一并提交		
谁进行知情同意（可多选）	√ 项目负责人 √ 研究者 √ 医生 ☐ 护士 ☐ 其他：_____		
知情同意形式	√ 纸版知情同意 ☐ 口头知情同意 ☐ 电子知情同意 ☐ 不适用（拟申请免除知情同意）		
知情同意是否涉及代理同意	☐ 是，请明确： ☐ 监护人/法定代理人； ☐ 其他（请注明）：_____ √ 否		
知情同意过程质量控制措施（请具体描述）	当面告知所进行实验内容，告知所可能出现的症状，请被告之人了解实验内容过程，在第三方人员在场下进行知情过程签署		
知情同意文档管理计划	对知情同意书进行整理归档保存		
与研究有关的医疗检查与治疗	√免费 ☐部分免费 ☐不免费 ☐不适用		
参加研究相关交通、	200 元/例	其他补偿	_____ 元/例

餐补等	☐ 无		☐ 无
八、特殊审查要求			
☐	申请免除知情同意过程		
☐	申请免除签署书面知情同意文件		
☐	申请开展在紧急情况下无法获得知情同意的研究		
☐	研究涉及弱势群体 →请明确： ☐儿童/未成年人 ☐服刑人员 ☐孕妇 ☐认知障碍或因健康状况而没有能力做出知情同意的成年人 ☐申办者/研究者的雇员或学生 ☐教育/经济地位低下的人员 ☐疾病终末期患者 ☐其他（请注明）：_____ 注：弱势群体是个相对概念。多指儿童、孕妇、胎儿、新生儿（不能存活或存活能力未知）、存在认知障碍的成年人、医学上不能够做出知情同意的成年人、由于语言不通存在交流障碍的人、老年人（>90 岁）、受教育程度低下/存在经济困难的人群、疾病终末期患者（预期寿命<3 个月），等。		
☐	研究涉及侵入性检查、放射性检查		
☐	研究涉及纯属研究目的且在常规医疗/体检之外进行生物标本采集		
☐	研究涉及人类遗传资源的采集和保藏（人类遗传资源是指含有人体基因组、基因及其产物的器官、组织、细胞、核酸制品等资源材料及其产生的信息资料）。 重要提示：请咨询南方科技大学科研部，提交相关材料（电话：18565858818）。		
☐	研究涉及干细胞		
九、送审文件（另附，参见附件“送审文件清单”）			
十、项目负责人声明：			
我确保该表格所有填写内容以及所有送审文件的真实性。 **我声明将遵循国际公认伦理准则、国内相关法规以及南方科技大学医学伦理委员会相关要求，开展本项研究。** 项目负责人签字：_____郭传飞_____； 日期：____2024-6-22_____			
申报单位意见		单位盖章	

主管领导签字		日期	年 月 日

附件：送审文件清单（请勾选所提交文件并填写版本信息）：

		文件名称
√	1	项目负责人专业履历（签名，签署日期）
√	2	项目负责人伦理培训证明
√	3	研究方案
√	4	知情同意书
□	5	研究病历和/或病例报告表
□	6	受试者日记卡
□	7	调查问卷
□	8	招募受试者的材料（包括广告等）
□	9	曾向其他机构伦理委员会提交申请的相关说明（附审查材料、审查决定文件）

注：1-3 项为必须提交，其余文件根据项目具体情况提交。

IRB of the Southern University of Science and Technology

Initial review application chart

1.General situation	
Project tile	Research on Pressure Sensing Based on Skin-Electrode Interfaces
Funding source	National Natural Science Foundation of China.
Principal investigator	Chuanfei Guo
Institution of PI	Southern University of Science and Technology
E-mail of PI	guocf@sustech.edu.cn
Contact Information	18124682257
Contacts	Tao Huang
E-mail of Contacts	huangt@sustech.edu.cn
Contact Information	13564852741
2. Funding Source Information	
√ Chinese government ☐ the United States Federal Government ☐ Foundation ☐ School project ☐ Postgraduate research project ☐ Enterprise ☐ Others	
Grant number	52073138
3. Researcher Conflict of Interest	

Please confirm whether the project leader, key participants, or other key personnel (or their immediate family members, etc.) have any of the following circumstances:

- Do they have any economic or intellectual interests, or receive any compensation from the project sponsor or from the drugs, devices, or technologies to be used in the research?
- Are they the inventor or patent holder of the drugs, devices, or technologies used in the study?
- Do they have, or are they expected to have within one year, any financial relationships with this research (e.g., consulting, speaking engagements, acting as an advisor, patents, equity, stock options, etc.)?

☐ Yes, Please complete and submit the "Statement of conflict of Interests" form.

√ No.

4. Key members of the research team (please add to the table as necessary based on the actual situation).

Name	Education	Specialization/ Title	Affiliated Institution	Role in the Project	Has the individual participated in ethics training in the past two years?
Chuanfei Guo	Ph.D.	Material science and engineering/ Professor	Southern University of Science and Technology	PI	Yes
Tao Huang	Ph.D.	Material science and engineering/ Research Assistant Professor	Southern University of Science and Technology	Project Collaborator	Yes
Yi Huang	M.S.	Cardiology/ Physician	Southern University of Science and Technology hospital	Project Collaborator	Yes

5.Is this research a multi-center study?

√ Yes; please fill in the table below with details of other centers (additional tables can be added as necessary).

□ No, fill the part 6 directly.

Research Center Name	Contact Person/Phone Number	Does this research center have an Ethics Committee?	If there is an Ethics Committee, please select:
Southern University of Science and Technology hospital	Yi Huang/ 13670029152	√Yes □No	□ The Ethics Committee will review this project. √ The Ethics Committee will accept the review decision of this Ethics Committee.

6. Research Summary (Please fill in each item. If a particular item is not applicable, write "N/A")

Research Design (You may select	√Case-Control Study □ Cohort Study □Cross-Sectional Study□Non-Randomized Controlled Study

multiple options)	√Randomized Controlled Study √Blinded Method Applied □Other:
Purpose of research	This project has developed an electrical stimulation patch for tactile enhancement, and the study aims to evaluate the effectiveness of this patches in patients with tactile impairments.
Subject Selection (Including inclusion and exclusion criteria)	Inclusion criteria: (1) This study will primarily select participants with tactile impairments resulting from diabetes, stroke, neurological diseases, or physical injuries. Participants should generally exhibit symptoms of tactile dysfunction or limb numbness. (2) The study will also invite individuals with normal tactile sensation as a control group. Exclusion Criteria: (1) Participants with severe skin lesions, including extensive skin ulceration or trauma, will be excluded. (2) Individuals with severe allergic conditions will also be excluded from the study.
Control Group	Healthy individuals with normal tactile function.
Intervention	None
Primary indicators	1. Current/weight threshold; 2. Location/shape recognition; 3. Other feels, like temperature perception.
Follow-up situation	None
Sample size	Within 50 samples
Statistical Analysis	Statistical significance will be set at a p-value < 0.05.
Risk Assessment	☑ Not greater than minimal risk □ Greater than minimal risk
Potential risks involved in the study include:	- Skin allergic reactions such as redness. - Pain caused by electrical stimulation.
Risk mitigation measures include: (Please provide specific details)	- In case of allergic symptoms: remove the patch and apply anti-allergy ointment. - In case of pain from electrical stimulation: reduce the current intensity.
Research benefits	□ Direct benefits; √ Indirect benefits; □ Both
Possible benefits of the research:	The research will help determine the target population for the skin patch developed in the project, contributing to the further development of the

	patch, publication of related articles, and future project applications.
Data security oversight plan (including privacy protection, data security, and other quality assurance measures, please describe specifically):	The data collected will only include photographs of the local skin condition of the subjects, and this data will not expose the subjects' personal identity information. The security of the data is therefore high.
Planned Research Duration	27th, Jun., 2024 to 1st, Dec., 2024
7. Subject Recruitment, Informed Consent, Costs, and Compensation	
Who is responsible for recruitment (You may select multiple options)	√ Principal Investigator √ Researcher √ Doctor □ Nurse □ Others：_____
Recruitment Methods (You may select multiple options)	☐ Recruitment notices √ Internet □ E-mail ☐ WECHAT ☐ SMS □ Others：____
Planned Recruitment Location (Please specify the exact locations, such as outpatient clinics, wards, etc.)	Outpatient Department, Southern University of Science and Technology Hospital
Will recruitment materials be used?	√ No □ Yes → Please submit them as part of the approval documents.
Who will obtain informed consent (You may select multiple options)	√ Principal Investigator √ Researcher √ Doctor □ Nurse □ Other：_____
Informed Consent Form	√ Paper-based informed consent □ Verbal informed consent □ Electronic informed consent □ Not applicable (exemption requested from informed consent
Does informed	□ Yes, please specify:

consent involve proxy consent?	□ Guardian/Legal Representative； □ Others：_____ √ No		
Quality control measures for the informed consent process (please describe specifically):	The study details and potential symptoms are explained in person to the participant. The participant is fully informed of the procedure, and the informed consent is signed in the presence of a third party to ensure transparency.		
Informed Consent Document Management Plan	The informed consent forms will be organized, archived, and securely stored.		
Medical examinations and treatments related to the study	√Free □Partially free □Not free □Not applicable		
Transportation, Meals, and Other Study-Related Compensation	200 Yuan/sample □ None	Other Compensation	_____ Yuan/sample √ None

8. Special Review Requirements	
□	Application for Exemption from the Informed Consent Process
□	Application for exemption from signing written informed consent forms
□	Application to conduct research where informed consent cannot be obtained in emergency situations
□	Research Involves Vulnerable Populations → Please specify: □Children/Minors □Incarcerated individuals □Pregnant women □Adults with cognitive impairments or those unable to provide informed consent due to health conditions □Employees or students of the sponsor/researchers □Individuals with low educational or economic status □End-of-life patients □Other (please specify):_____ Note: Vulnerable populations is a relative concept, generally referring to children, pregnant women, fetuses, newborns (unable to survive or with unknown survival potential), adults with cognitive impairments, adults who are medically incapable of providing informed consent, individuals with communication barriers (e.g., due to language differences), elderly individuals (>90 years old), those with low educational levels or economic hardship, end-

	of-life patients (life expectancy < 3 months), etc.
□	Research involves invasive procedures or radiological examinations
□	Research involves the collection of biological samples for purely research purposes, outside of routine medical exams or checkups
□	Research involves the collection and preservation of human genetic resources (human genetic resources refer to materials such as organs, tissues, cells, nucleic acid products, etc., that contain human genomic information, genes, and their products, as well as the data generated from them). Important Notice: Please consult the Research Department of Southern University of Science and Technology and submit the relevant materials (Phone: 18565858818).
□	Research involves stem cells

9. Submission Documents for Review (See attached documents)

10. Statement of the Principal Investigator:

I ensure the accuracy and truthfulness of all the information provided in this form and all submission documents.

I declare that I will conduct this research in accordance with internationally recognized ethical guidelines, relevant domestic regulations, and the requirements of the Southern University of Science and Technology Medical Ethics Committee.

Principal Investigator：__Chuanfei Guo__； Data：____2024-6-22_____

Opinion of the Applicant Institution		Institutional Stamp	
Signature of the Supervising Leader		Data	

Attachments: Submission Document Checklist

(Please check the submitted documents and provide version information):

		Document Name
√	1	Principal Investigator's Professional Resume (Signature, Signing Date)
√	2	Principal Investigator's Ethics Training Certificate
√	3	Research Protocol

√	4	Informed Consent Form
□	5	Research Medical Records and/or Case Report Forms
□	6	Subject Diary Cards
□	7	Survey Questionnaire
□	8	Recruitment Materials (including advertisements, etc.)
□	9	Explanation of previous submissions to other Ethics Committees (including review materials, review decision documents)

Note: Items 1-3 are required to be submitted, and other documents should be submitted based on the specifics of the project.

南方科技大学医学伦理审查表决书

决议编号	20240220
项目名称	基于皮肤-电极界面的压力传感研究
受理编号	2024PES220
申请时间	2024 年 6 月 22 日
是否通过初审	□通过√ □不通过
会议或通讯审查的时间	2024 年 6 月 27 日
伦理审查结果	□通过 √ □修改再审查 □不通过
伦理委员会审批意见： 同意，项目执行符合科技伦理规范。 2024 年 6 月 27 日	

IRB of the Southern University of Science and Technology

Review Voting Document

Decision serial number	20240220
Project's title	Pressure Sensing Based on the Skin-electrode Interface
Acceptance serial number	2024PES220
Time of application	22nd, June, 2024
If it passed the first review	☐Approve✓ ☐Disapprove
Data of meeting and review	27th, June, 2024
Ethical review results	☐Approve✓ ☐Re-examination after modification. ☐Disapprove
Decision committed by ethics committee: Approved, the project complies with scientific and technological ethics standards. 南方科技大学 医学伦理委员会 2024年6月27日	