## 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	2021A1515110862		
号)			

#### 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 程/教	科学与工 対授	南方科技	大	项目负责人	是
五、该研究	是否	是多口	<b>卢心</b> 矽	肝究?					
□ 是;	请填:	写下表	其他	中心概	既况(可根据	居实际情况增	加	表格)	
√ 否, <sup>-</sup>	请直:	接填写	第六	部分					
研究中心名	3称	联系	人/目	电话		心内是否有 表员会?	女	口果 <b>有</b> 伦理委员	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	F决定
六、研究推	<b>夢</b> (	请逐项	页填写	,若	某项不涉及	,填写"无	")		
研究设计			√病	√病例对照研究 □队列研究					
(可多选)			□横断面研究  □非随机对照研究						
, , , , , , , , , , , , , , , , , , ,			□随机对照研究 □应用盲法						
			口非	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			处于	触觉	障碍中人群	,包含糖尿病	病患	是者、周遭神经	经损伤患者等
(包括入排	<b></b>	E)							
对照设置				位健康	人群。				
干预措施			无						
主要观察指	<b></b>		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					□大于最小				
研究可能涉及的风		皮朋	t过敏 <sup>,</sup>	性发红、电	刺激带来的绸	<b>庝</b> 掮	<b></b>		
险包括:									
风险控制措		见括:	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			直接芽	<b>注益;</b> ✓	间接获益;		两者都有		

研究可能的获益	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
是:	一步发展、文章发表以及相关项目申请起到积极租用
(请具体描述)	
数据安全监管计划	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
(隐私保护、数据	试者的身份信息,数据安全性较高
   安全等质量保障措	
   施等,请具体描	
述)	
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	青同意、费用和补偿
谁负责招募	√ 项目负责人 ✓ 研究者 □ 医生 □ 护士
(可多选)	□ 其他:
招募方式(可多	□ 招募启事 ✓ 互联网 □ 电子邮件 ✓ 微信
选)	□ 手机短信 □其他(请注明):
计划招募地点(请	南方科技大学专家公寓
填写具体场所,如	
门诊、病房等)	
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	√ 项目负责人 ✓ 研究者 □ 医生 □ 护士
(可多选)	□ 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	□ 是,请明确:
代理同意	□ 监护人/法定代理人; □ 其他 (请注明):
	√ 否
知情同意过程质量	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
控制措施(请具体	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
描述)	
知情同意文档管理	对知情同意书进行整理归档保存
计划	
与研究有关的医疗	✓ 免费 □部分免费 □不免费 □不适用
检查与治疗	
参加研究相关交通、	500 元/例 其他补偿 元/例
餐补等	70/ PI
	口无

八、特殊审查	f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	f人声明:				
我确保该	<b>该表格所有填写内容以及所有送审文件的真实性。</b>				
我声明将	<b>F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</b>				
相关要求,チ	F展本项研究。				
项目负责	· 人签字:				
申报单位意见	L 单位盖章				
, 4,4 ) [272,7]	, , , , , , , , , , , , , , , , , , , ,				
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。

## 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 Informa	tion			
√ Chinese government □	the United States Federal Government			
☐ Foundation ☐ Sc	chool project			
☐ Postgraduate research pro	oject □ Enterprise □ Others			
Grant number	Grant number 2021A1515110862			
3. Researcher Conflict of Int	terest			
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	project sponsor or from the drugs, devices, or technologies to be used in the research?			
Are they the inventor or	• Are they the inventor or patent holder of the drugs, devices, or technologies used in the			
study?				
Do they have, or are the	ey expected to have within one year, any financial relationships			
with this research (e.g.,	with this research (e.g., consulting, speaking engagements, acting as an advisor, patents,			
equity, stock options, et	c.)?			
☐ Yes, Please comple	te and submit the "Statement of conflict of Interests" form.			
√ No.				
4. Key members of the res	earch team (please add to the table as necessary based on the			

actual situa	ation	).						
Name	Edu	ıcation	Speci Title	alization/	Affiliated Institution		Role in the Project	Has the individual participated in ethics training in the past two years?
Chuanfei Guo	Ph.D.		Mater science engine	ce and eering/	Southern University Science a Technology	nd	ΡΙ	Yes
Tao Huang	Ph.D.		science engin Resea Assis	gineering/ University		nd	Project Collaborator	Yes
5.Is this research a multi-center study?								
□ Yes; plea	se fil	ll in the tab	le belo	ow with det	ails of other	cei	nters (addition	al tables can be
added as n	ecess	ary).						
√ No, fill	the j	part 6 direc	tly.					
Researc Center Na			Does this research center have an Ethics Committee?			there is an Etl	nics Committee,	
				□Yes	□No	re  ac	view this project	Committee will decision of this
6. Research	h Sun	nmary (Ple	ase fill	in each ite	m. If a parti	cula	ar item is not a	pplicable, write

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

Research Design	√Case-Control Study	□ Cohort Study
(You may select	□Cross-Sectional Study□No	on-Randomized Controlled Study
multiple options)	□Randomized Controlled St	udy □Blinded Method Applied
	□Other:	

D.,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	This project has developed an electrical elimination metals C + + +1
1 1	This project has developed an electrical stimulation patch for tactile
	enhancement, and the study aims to evaluate the effectiveness of this
<u> </u>	patches in patients with tactile impairments.
	Inclusion criteria:
	(1) This study will primarily select participants with tactile impairments
<u> </u>	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
8	as a control group.
I	Exclusion Criteria:
	(1) Participants with severe skin lesions, including extensive skin
ι	ulceration or trauma, will be excluded.
	(2) Individuals with severe allergic conditions will also be excluded
f	from the study.
Control Group I	Healthy individuals with normal tactile function.
Intervention 1	None
Primary indicators	1. Current/weight threshold;
2	2. Location/shape recognition;
Follow-up situation	None
Sample size	Within 5 samples
Statistical Analysis I	P-value statistical analysis was performed on the data.
	1
Risk Assessment [	✓ Not greater than minimal risk   □ Greater than minimal risk
Potential risks -	✓ Not greater than minimal risk ☐ Greater than minimal risk
Potential risks -	✓ Not greater than minimal risk ☐ Greater than minimal risk - Skin allergic reactions such as redness.
Potential risks - involved in the study include:	✓ Not greater than minimal risk ☐ Greater than minimal risk - Skin allergic reactions such as redness.
Potential risks - involved in the study - include:  Risk mitigation -	<ul> <li>✓ Not greater than minimal risk</li> <li>– Skin allergic reactions such as redness.</li> <li>– Pain caused by electrical stimulation.</li> </ul>
Potential risks - involved in the study - include:  Risk mitigation - measures include:	✓ Not greater than minimal risk ☐ Greater than minimal risk  - Skin allergic reactions such as redness.  - Pain caused by electrical stimulation.  - In case of allergic symptoms: remove the patch and apply anti-allergy
Potential risks - involved in the study - include:  Risk mitigation - measures include:	✓ Not greater than minimal risk ☐ Greater than minimal risk  - Skin allergic reactions such as redness.  - Pain caused by electrical stimulation.  - In case of allergic symptoms: remove the patch and apply anti-allergy ointment.
Potential risks involved in the study include:  Risk mitigation measures include: (Please provide specific details)	✓ Not greater than minimal risk ☐ Greater than minimal risk  - Skin allergic reactions such as redness.  - Pain caused by electrical stimulation.  - In case of allergic symptoms: remove the patch and apply anti-allergy ointment.
Potential risks involved in the study include:  Risk mitigation measures include: (Please provide specific details)  Research benefits	<ul> <li>✓ Not greater than minimal risk</li> <li>Skin allergic reactions such as redness.</li> <li>Pain caused by electrical stimulation.</li> <li>In case of allergic symptoms: remove the patch and apply anti-allergy ointment.</li> <li>In case of pain from electrical stimulation: reduce the current intensity.</li> </ul>
Potential risks involved in the study include:  Risk mitigation measures include:  (Please provide specific details)  Research benefits  Possible benefits of	<ul> <li>✓ Not greater than minimal risk</li></ul>
Potential risks involved in the study include:  Risk mitigation measures include:  (Please provide specific details)  Research benefits  Possible benefits of the research:	<ul> <li>✓ Not greater than minimal risk</li></ul>
Potential risks involved in the study include:  Risk mitigation measures include: (Please provide specific details)  Research benefits  Possible benefits of the research:	<ul> <li>✓ Not greater than minimal risk</li></ul>

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

measures for the informed consent process (please	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.				
describe specifically	):				
Informed Consent	The informed consent forms will be organized, archived, and securely				
Document	stored.				
Management Plan					
Medical examination	ns				
and treatments relate	, 11				
to the study					
Transportation,	500 Yuan/sample Other Yuan/sample				
Meals, and Oth	Compensation				
Study-Related	□ None				
Compensation					
8. Special Review R					
	ication 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				
	mergency situations				
	Research Involves Vulnerable Populations → Please specify:				
	Children/Minors □Incarcerated individuals □Pregnant women				
	□Adults with cognitive impairments or those unable to provide inform				
	nsent due to health conditions				
	Employees or students of the sponsor/researchers  ndividuals with low educational or economic status				
	End-of-life patients Other (please specify):				
	ote: Vulnerable populations is a relative concept, generally referring to				
	ildren, pregnant women, fetuses, newborns (unable to survive or with				
	unknown survival potential), adults with cognitive impairments, adults who are				
	edically incapable of providing informed consent, individuals with				
	mmunication barriers (e.g., due to language differences), elderly individuals				
	90 years old), those with low educational levels or economic hardship, end-				
	life patients (life expectancy < 3 months), etc.				
□ Rese	Research involves invasive procedures or radiological examinations				
□ Rese	arch 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
$\checkmark$	1	Principal Investigator's Professional Resume (Signature, Signing Date)
	2	Principal Investigator's Ethics Training Certificate
	3	Research Protocol
$\checkmark$	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

	197					
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					
	□通过 √					
伦理审查结果	□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。



# **Review Voting Document**

Decision serial number	20240005
Project's title	Adhesive Electrode for Iontronic Sensing Structure
Acceptance serial number	2024PES005
Time of application	4 <sup>th</sup> , January, 2024
If it passed the first review	□Approve✓
	□Disapprove
Data of meeting and review	10 <sup>th</sup> , January, 2024
Ethical review results	□Approve✓
	□Re-examination after modification.
<b>D</b> 11 11 11	□Disapprove
Decision committed by ethic	s committee:
Approved, the project comp standards.	plies with scientific and technological ethics
	作型 月 月 4年

## 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	52073138			
号)				

#### 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	E			物理化学究助理教	南方科技	大	项目协调人	是
黄毅	博二	t		心内	科/医师	南方科技	大	项目合作者	是
五、该研究	7.是不	是多中	卜心砌	肝究?					
√ 是; ो	请填:	写下表	其他	中心机	既况(可根据	居实际情况增	加	表格)	
口 否,i	请直:	接填写	第六	部分					
研究中心名	3称	联系	人/目	电话		心内是否有 表员会?	女	口果 <b>有</b> 伦理委员	员会,请选择:
南方科技力	<b>大学</b>	黄		毅	<b>√</b> 有	 □无		] 该伦理委员	会将对该项目
医院		/1367	70029	152	( 7 行		进	行审查	
							√	该伦理委员	会将接受本伦
							理	里委员会的审查决定	
六、研究撤	要(	(请逐项	页填写	3,若	某项不涉及	.,填写 "无·	")		
研究设计			√病例对照研究 □队列研究						
(可多选)			□横断面研究   □非随机对照研究						
(円多匹)			√随机对照研究 ✓应用盲法						
			□其他:						
研究目的			本項	同开.	发了一种用	于触觉增强的	的电	且刺激贴片,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	Ē		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						
(包括入排	<b>非标准</b>	E)							
对照设置			触觉	位健康.	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		皮朋	快过敏·	性发红、电	刺激带来的绸	庝掮	<b></b>		
险包括:									
风险控制措	风险控制措施包括:		若发	生过	敏症状: 撕	去贴片、擦扎	式去	云过敏药膏;	

(请具体描述)	若发生电刺激痛感:降低电流		
研究获益属于	□ 直接获益; ✓ 间接获益	益; □ 两者都有	Ī
研究可能的获益	对项目制备的皮肤贴片适用人	人群起到决定作用	1,为后续该贴片的进
是:	一步发展、文章发表以及相关	失项目申请起到积	?极租用
(请具体描述)			
数据安全监管计划	所获得数据仅包含受试者局部	邓皮肤状态照片,	该数据将不会暴露受
(隐私保护、数据	试者的身份信息,数据安全性	性较高	
安全等质量保障措			
施等,请具体描			
述)			
计划研究时间	2024年6月27日至 2024	4年8月1日	
七、受试者招募、知			
谁负责招募	√ 项目负责人 ✓ 研究者	者 ✓ 医生	□ 护士
(可多选)	□ 其他:		
招募方式(可多	□ 招募启事 ✓ 互耳	联网 □ 电子	上邮件 √ 微信
选)	□ 手机短信 □其他	也(请注明):	_
计划招募地点(请	南方科技大学医院门诊		
填写具体场所,如			
门诊、病房等)			
是否使用招募材料	√否 □是 →请作为送审立	文件一并提交	
谁进行知情同意	√ 项目负责人 ✓ 研究者	考 ✓ 医生	□ 护士
(可多选)	□ 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i	青免除知情同意)
知情同意是否涉及	□ 是,请明确:		
代理同意	□ 监护人/法定代理人;	□ 其他(请注明	明):
	√ 否		
知情同意过程质量	当面告知所进行实验内容,		
控制措施(请具体	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
描述)			
知情同意文档管理	对知情同意书进行整理归档仍	呆存	
计划			
与研究有关的医疗	√免费 □部分免费 □ <sup>2</sup>	不免费 □不适	· 田
检查与治疗			
参加研究相关交通、	元/例	其他补偿	元/例

餐补等		□ 无			□ 无		
八、特殊审查	医要求						
	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	申请开展在紧急情况下无法获得知情同意的研究					
	研究涉	研究涉及弱势群体 →请明确:					
	口儿	童/未成年人 □服用	引人	.员 □孕妇			
	□认	知障碍或因健康状况而没	有角	能力做出知情同意的	的成年人		
	□申	办者/研究者的雇员或学生	Ė.				
	□教	育/经济地位低下的人员					
	□疾	病终末期患者					
	口其	他 (请注明):					
	注:	弱势群体是个相对概念。	多扌	旨儿童、孕妇、胎儿	、新生儿 (不能存活		
	或存	活能力未知)、存在认知[	章码	<b>P</b> 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	交汇	<b>流障碍的人、老年</b> 人	、(>90岁)、受教育		
	程度	低下/存在经济困难的人都	¥、	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	庁/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	蔵(人类遗传资源是	是指含有人体基因组、		
	基因及	其产物的器官、组织、细胞	ė,	核酸制品等资源材	料及其产生的信息资		
	料)。						
	重要提	显示:请咨询南方科技	大'	学科研部,提交	相关材料(电话:		
	185658	58818)。					
	研究涉	及干细胞					
九、送审文件	件(另附,	, 参见附件"送审文件清	单"	<b>'</b> )			
十、项目负责	長人声明:	•					
我确保证	<b>亥表格</b> 所	有填写内容以及所有送审	文化	牛的真实性。			
我声明料	<b>将遵循国</b>	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	干展本项	研究。					
项目负责	5人签字: 「	:郭传飞	_;	日期 <b>:</b>	2024-6-22		
申报单位意见	ī.			单位盖章			

主管领导签字	日期	年月	日
		i	

## 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。

## 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 Informa	tion					
√ Chinese government □	the United States Federal Government					
☐ Foundation ☐ Sc	chool project					
☐ Postgraduate research pro	pject □ Enterprise □ Others					
Grant number	52073138					
<b>3.</b> Researcher Conflict of Int	erest					
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 econo	omic 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 the	ey expected to have within one year, any financial relationships					
with this research (e.g.,	with this research (e.g., consulting, speaking engagements, acting as an advisor, patents,					
equity, stock options, et	equity, stock options, etc.)?					
☐ Yes, Please complete and submit the "Statement of conflict of Interests" form.						
√ No.	√ No.					
4. Key members of the res	earch 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/	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?

 $\sqrt{\text{Yes}}$ ; 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	Yi Huang/	√Yes ⊓No	☐ The Ethics Committee will
University of	13670029152	VICS LIVE	review this project.
Science and			√ The Ethics Committee will
Technology			accept the review decision of this
hospital			Ethics Committee.

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

Research Design	√Case-Control Study	□ Cohort Study
(You may select	□Cross-Sectional Study□No	n-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	Inclusion criteria:
(Including inclusion	(1) This study will primarily select participants with tactile impairments
and exclusion criteria)	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;
Primary indicators	<ol> <li>Current/weight threshold;</li> <li>Location/shape recognition;</li> </ol>
Primary indicators	_
Primary indicators  Follow-up situation	2. Location/shape recognition;
·	<ul><li>2. Location/shape recognition;</li><li>3. Other feels, like temperature perception.</li></ul>
Follow-up situation	<ul><li>2. Location/shape recognition;</li><li>3. Other feels, like temperature perception.</li><li>None</li></ul>
Follow-up situation Sample size	<ul><li>2. Location/shape recognition;</li><li>3. Other feels, like temperature perception.</li><li>None</li><li>Within 50 samples</li></ul>
Follow-up situation Sample size Statistical Analysis	2. Location/shape recognition; 3. Other feels, like temperature perception.  None  Within 50 samples  Statistical significance will be set at a p-value < 0.05.
Follow-up situation Sample size Statistical Analysis Risk Assessment	<ul> <li>2. Location/shape recognition;</li> <li>3. Other feels, like temperature perception.</li> <li>None</li> <li>Within 50 samples</li> <li>Statistical significance will be set at a p-value &lt; 0.05.</li> <li>☑ Not greater than minimal risk ☐ Greater than minimal risk</li> </ul>
Follow-up situation Sample size Statistical Analysis Risk Assessment Potential risks	<ul> <li>2. Location/shape recognition;</li> <li>3. Other feels, like temperature perception.</li> <li>None</li> <li>Within 50 samples</li> <li>Statistical significance will be set at a p-value &lt; 0.05.</li> <li>☑ Not greater than minimal risk ☐ Greater than minimal risk</li> <li>- Skin allergic reactions such as redness.</li> </ul>
Follow-up situation Sample size Statistical Analysis Risk Assessment Potential risks involved in the study	<ul> <li>2. Location/shape recognition;</li> <li>3. Other feels, like temperature perception.</li> <li>None</li> <li>Within 50 samples</li> <li>Statistical significance will be set at a p-value &lt; 0.05.</li> <li>☑ Not greater than minimal risk ☐ Greater than minimal risk</li> <li>- Skin allergic reactions such as redness.</li> </ul>
Follow-up situation Sample size Statistical Analysis Risk Assessment Potential risks involved in the study include:	<ul> <li>2. Location/shape recognition;</li> <li>3. Other feels, like temperature perception.</li> <li>None</li> <li>Within 50 samples</li> <li>Statistical significance will be set at a p-value &lt; 0.05.</li> <li>☑ Not greater than minimal risk ☐ Greater than minimal risk</li> <li>- Skin allergic reactions such as redness.</li> <li>- Pain caused by electrical stimulation.</li> </ul>
Follow-up situation Sample size Statistical Analysis Risk Assessment Potential risks involved in the study include: Risk mitigation	<ul> <li>2. Location/shape recognition;</li> <li>3. Other feels, like temperature perception.</li> <li>None</li> <li>Within 50 samples</li> <li>Statistical significance will be set at a p-value &lt; 0.05.</li> <li>☑ Not greater than minimal risk ☐ Greater than minimal risk</li> <li>- Skin allergic reactions such as redness.</li> <li>- Pain caused by electrical stimulation.</li> <li>- In case of allergic symptoms: remove the patch and apply anti-allergy</li> </ul>
Follow-up situation Sample size Statistical Analysis Risk Assessment Potential risks involved in the study include: Risk mitigation measures include:	<ul> <li>2. Location/shape recognition;</li> <li>3. Other feels, like temperature perception.</li> <li>None</li> <li>Within 50 samples</li> <li>Statistical significance will be set at a p-value &lt; 0.05.</li> <li>☑ Not greater than minimal risk ☐ Greater than minimal risk</li> <li>- Skin allergic reactions such as redness.</li> <li>- Pain caused by electrical stimulation.</li> <li>- In case of allergic symptoms: remove the patch and apply anti-allergy ointment.</li> </ul>
Follow-up situation Sample size Statistical Analysis Risk Assessment Potential risks involved in the study include: Risk mitigation measures include: (Please provide	<ul> <li>2. Location/shape recognition;</li> <li>3. Other feels, like temperature perception.</li> <li>None</li> <li>Within 50 samples</li> <li>Statistical significance will be set at a p-value &lt; 0.05.</li> <li>☑ Not greater than minimal risk ☐ Greater than minimal risk</li> <li>- Skin allergic reactions such as redness.</li> <li>- Pain caused by electrical stimulation.</li> <li>- In case of allergic symptoms: remove the patch and apply anti-allergy ointment.</li> </ul>
Follow-up situation Sample size Statistical Analysis Risk Assessment Potential risks involved in the study include: Risk mitigation measures include: (Please provide specific details)	<ul> <li>2. Location/shape recognition;</li> <li>3. Other feels, like temperature perception.</li> <li>None</li> <li>Within 50 samples</li> <li>Statistical significance will be set at a p-value &lt; 0.05.</li> <li>☑ Not greater than minimal risk ☐ Greater than minimal risk</li> <li>- Skin allergic reactions such as redness.</li> <li>- Pain caused by electrical stimulation.</li> <li>- In case of allergic symptoms: remove the patch and apply anti-allergy ointment.</li> <li>- In case of pain from electrical stimulation: reduce the current intensity.</li> </ul>

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

consent involve proxy		□ Guardian/Legal Representative; □ Others:			
consent?		√ No			
Quality control		The study details and potential symptoms are explained in person to			
measures for the		the participant. The participant is fully informed of the procedure,			
informed cons	sent		nformed consent is insparency.	s signed in the prese	nce of a third party to
process (pleas	se	clisure tra	insparency.		
describe speci	ifically):				
Informed Con	sent	The inform	med consent forms	s will be organized,	archived, and securely
Document		stored.			
Management	Plan				
Medical exam	inations	√Free	□Partially free	□Not free □Not ap	mlicable
and treatments	s related	VITCC	in artially free	inot nee inot ap	орнеаоте
to the study					
Transportation	n,	200	Yuan/sample	Other	Yuan/sample
Meals, and	Other	200	Tuan/sampic	Compensation	ruan/sample
Study-Related	1	□ None		Compensation	√ None
Compensation	1				
8. Special Re	view Req	uirements			
	Applica	tion for Ex	emption from the l	Informed Consent P	rocess
	Applica	tion for exe	emption from signi	ing written informed	l consent forms
	Applica	tion to con-	duct research when	re informed consent	cannot be obtained in
	emergency situations		ns		
	Resea	arch Involv	es Vulnerable Pop	ulations → Please s <sub>l</sub>	pecify:
	□Chi	ldren/Minoi	rs   Incarcerated	individuals □Pregna	nt women
	□Adı	ults with cognitive impairments or those unable to provide informed			
	conse	ent due to health conditions			
	□Emj	ployees or students of the sponsor/researchers			
	□Indi	ividuals with low educational or economic status			
	□End	d-of-life patients			
	□Oth	er (please s	pecify):		
	Note:	Vulnerabl	e populations is a	a relative concept,	generally referring to
	child	ren, pregna	nt women, fetuse	s, newborns (unabl	e to survive or with
	unkn	own surviva	al potential), adults	with cognitive impai	rments, adults who are
	medi	cally incap	pable of providir	ng informed conse	ent, individuals with
	comn	nunication b	parriers (e.g., due to	o language difference	es), 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 sample	s for purely research	
	purposes, outside of routine medical ex	xams or checkups		
	Research involves the collection and	preservation of hu	man genetic resources	
	(human genetic resources refer to mate	erials such as organs	s, tissues, cells, nucleic	
	acid products, etc., that contain huma	an genomic informa	ation, genes, and their	
	products, as well as the data generated	from them).		
	Important Notice: Please consult to	the Research Dep	artment of Southern	
	University of Science and Technology	and submit the rele	vant materials (Phone:	
	18565858818).			
	Research involves stem cells			
9. Submission Documents for Review (See attached documents)				
9. Submission	1 Documents for Review (See attached	documents)		
	t of the Principal Investigator:	i documents)		
	·	documents)		
10. Statemen	·		vided in this form and	
10. Statemen	t of the Principal Investigator:		rided in this form and	
10. Statemen  I ensure all submission	t of the Principal Investigator:	e information prov		
I ensure all submission	t of the Principal Investigator: the accuracy and truthfulness of all th	e information prov	nationally recognized	
I ensure all submission I declare ethical guide	t of the Principal Investigator:  the accuracy and truthfulness of all the documents.  that I will conduct this research in acc	e information prov ordance with inter and the requirem	nationally recognized	
I ensure all submission I declare ethical guide	t of the Principal Investigator:  the accuracy and truthfulness of all the documents.  that I will conduct this research in accuracy, relevant domestic regulations,	e information prov ordance with inter and the requirem	nationally recognized	
I ensure all submission I declare ethical guide University of	t of the Principal Investigator:  the accuracy and truthfulness of all the documents.  that I will conduct this research in accuracy, relevant domestic regulations,	e information prov ordance with inter and the requirem	nationally recognized ents of the Southern	
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**Attachments: Submission Document Checklist** 

Supervising Leader

### (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√
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。



# **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	22 <sup>nd</sup> , June, 2024
If it passed the first review	□Approve✓
	□Disapprove
Data of meeting and review	
	27 <sup>th</sup> , 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.	
	医学化注入