IRB 审核编码(IRB NO.)： HYIRB-61202303211 申请日期（Date of Application)： 2022-03-13

幻夜心理集团人因科学研究项目伦理审核申请表

(IRB Request Form of Human Factors Research of HuanYe Psychology Group Application)

基本信息(GENERAL INFORMATION)

1. 课题题目(Research Title)

民航领域内模拟创伤范式诱发PTSS的素材库的建立

Establishment of a Material Database for PTSS Induced by Analogue Trauma Paradigm in the Field of Civil Aviation

2. 课题阶段(Phased Research Overview)

本研究分为两个阶段，第一个阶段为对模拟范式的应用情况发展，不发表成果。第二阶段基于第一阶段的研究与分析，提出新的、适用于民航领域内的模拟创伤范式的PTSS素材库，并以论文形式发表成果。

This study is divided into two stages. The first stage is the development of the application of simulation paradigm, and the results are not published. In the second stage, based on the research and analysis in the first stage, a new PTSS material database suitable for the analogue trauma paradigm in the field of civil aviation was proposed, and the results were published in the form of papers.

注： 与这项课题类似或相关的前序课题是否已通过集团研究伦理委员会审核？

Note: Have any similar or related prior studies to this project been reviewed and approved by the group research IRB?

☐是(Yes)，IRB审核编码(IRB Code)： ☑否(No)

3. 研究人员(Researchers)

研究参加人员包括所有与实验被试或者实验数据有直接接触的人员。

Research participants include all individuals who have direct contact with either the experimental subjects or the experimental data.

3a. 负责人(Principal Investigator)

姓名(Name)： 王新/Xin Wang	部门(Institute)： 甘肃一如律师事务所/Gansu Yiru Law Firm 中国民用航空飞行学院应用心理学系/Department of Applied Psychology, Civil Aviation Flight University of China
电子邮箱(E-mail)： wxinlawyer@outlook.com	手机(Cell)： +86-18993874494

3b. 参加人员与阶段(Participating Researchers)

姓名(Name)：	参加研究单位(Institute)	阶段（Phased）
1.王新/Xin Wang	甘肃一如律师事务所/Gansu Yiru Law Firm 中国民用航空飞行学院/CAFUC	所有阶段/All phases
2.王翔/Xiang Wang	中国民用航空飞行学院/CAFUC	所有阶段/All phases
3.孟豫/Yu Meng	中国民用航空飞行学院/CAFUC	第二阶段/Phase II
4.张婴晨/Zhaochen Zahng	中国民用航空飞行学院/CAFUC	第二阶段/Phase II
5.董怡然/Yiran Dong	江苏师范大学/JSNU	第二阶段/Phase II
6.肖琪林/Qilin Xiao	中国民用航空飞行学院/CAFUC	所有阶段/All phases

超过6人的，第7人开始请附表并注明

Starting from the 7th person, please attach the table and specify

4. 主要经费来源(Major Funding Source)

名称： 中国民用航空飞行学院航空心理科研基金/Aeronautical Psychology Research Fund of CAFUC	额度： 依照出版费用/Based on publication costs
单位： 中国民用航空飞行学院/CAFUC	时间： 2022-03

请回收 Please recycle

是否申请审核豁免(Is Review Exemptions?)

部分有人类被试参与的研究可以申请审核豁免，这可以减少申请和审核的要求，加快审核的速度。请求审核豁免的研究者请在以下空白陈述豁免理由。【注：仅针对二手数据(如集团已有的档案、量表数据等，需进行数据脱敏)】

Research involving human participants in certain cases may apply for review exemption, which can reduce the requirements for application and review, and expedite the review process. Researchers requesting review exemption are kindly asked to provide the rationale for exemption in the space below. [Note: This applies only to secondary data (e.g., existing archives, questionnaire data, etc., requiring data anonymization).]

不申请/Not applying

研究课题介绍(Research Project Introduction)

1. 研究目标(Specific Aims) (限 300 字)

建立一个民航领域能够科学、高效和经济的，以模拟创伤范式为基本范式的适用于人为、有限制的诱发航空人员特殊情境下的创伤后应激反应（PTSS）的数据库。

Establish a scientific, efficient, and economic database in the aviation domain with analogue trauma paradigm as the core framework, suitable for inducing post-traumatic stress symptoms (PTSS) in aviation personnel under specific scenarios under controlled conditions.

2. 研究背景和研究意义(Background and Significance) (限 600 字)

民航飞行员、管制员等相关人员长期处于高压认知负荷下工作，在突发事件发生时容易引发创伤后应激症状（PTSS）。ICAO将应激症状定义为飞行安全极高风险的来源。如何在理论研究和实验室条件下触发民航人员PTSS，是研究PTSS对民航飞行安全影响的最基础的一步。

Lazarus及其同事于1964年建立了模拟创伤范式，并在随后的几年中继续发展。Horowitz在PTSS研究中首次引入该范式，并证实该范式能有效诱导健康受试者出现PTSS样症状。近年来，许多研究者将模拟创伤范式应用于PTSS、ASD和PTSD的研究中，均证明该范式能有效诱导PTSS。然而，现有的模拟创伤范式材料数据库与民航领域相关人员的应激情景关系不密切，导致该范式无法有效应用于民航领域PTSS相关研究。

我们认为有必要建立一个科学、高效、经济的与民航特殊情况相关的模拟创伤数据库。这将使所有民航人为因素研究人员能够更广泛地研究PTTS如何影响飞行员的操作、空管人员的指挥决策等相关问题，从而更好地促进民航安全的持续发展。

Aviation pilots, air traffic controllers, and others are frequently exposed to high cognitive workloads, making them prone to developing post-traumatic stress symptoms (PTSS) during emergencies. The International Civil Aviation Organization (ICAO) identifies stress symptoms as a significant source of high risk to flight safety. Triggering PTSS in aviation personnel under theoretical research and laboratory conditions is the foundational step in studying the impact of PTSS on aviation safety.

Lazarus and his colleagues established the analogue trauma paradigm in 1964 and further developed it in subsequent years. Horowitz was the first to introduce this paradigm into PTSS research and confirmed its effectiveness in inducing PTSS-like symptoms in healthy subjects. In recent years, many researchers have applied the analogue trauma paradigm to studies on PTSS, ASD, and PTSD, all of which have demonstrated its effectiveness in inducing PTSS. However, the existing analogue trauma paradigm material database is not closely related to the stress scenarios of aviation professionals, resulting in the paradigm's inability to be effectively applied to PTSS-related research in the aviation field.

We believe it is necessary to establish a scientific, efficient, and economical analogue trauma database related to aviation special circumstances. This will enable all aviation human factors researchers to more extensively investigate how PTTS affects pilots' operations, air traffic controllers' command decisions, and related issues, thereby better promoting the sustained development of aviation safety.

3. 研究被试(Research Participants)

请提供研究被试的人数、年龄阶段，并注明本研究是否旨在招募有特殊需要的人群。

Please provide the number of research participants, their age groups, and whether this study aims to recruit individuals with special needs.

3a. 被试数 (Number of Participants)

不考虑被试流失的情况下，最多招募120名被试。

Without considering participant dropout, up to 120 participants can be recruited.

3b. 被试类型(Types of Participants)

成人 Adult

☑ 18-64 岁 Adults (18-64)

☐ 65 岁(含）以上 Adults(65+)

未成年人 Pediatric

☐ 新生儿/婴儿 Newborns/Infants

☐ 学龄前儿童(2-5 岁) Preschool Children (2-5)

☐ 学龄儿童青少年(6- 18 岁) School-age Children and Adolescents (6- 18)

脆弱性 Vulnerability

☑ 健康志愿者 Healthy Volunteers

☐ 亚临床受试者 Preclinical 具体类型:_____

☐ 物理障碍，如脊髓受损 Physically Disabled, e.g., spinal cord injury

☐ 其他， 请说明 Other, specify:_____

3c. 被试来源(Source of Participants)

☐ 基层护理医生/专科医生 Primary Physician/Physician Specialist

☐ 急救室 Emergency Room

☐ 住院病人 Inpatients

☐ 人口调查/公共记录/商业邮件列表 Census/Public Records/Commercial Mail Lists

☐ 医疗记录/病人数据库 Medical Records/Patient Databases

☑ 报纸/电台/电视广告 Newspaper/Radio/Television Advertising

☑ 学校内张贴 Postings within School(s)

☐ 电子邮件声明 E-Mail Announcements

☑ 因特网站 Internet Sites

☐ 其他， 请说明 Other, specify:_____

注：所有用于招募被试的广告和信件文本均应提交审议

NOTE: The text of all advertisements and letters used to recruit subjects must be submitted for IRB approval.

3d. 被试入选条件 (Inclusion Criteria)

参与者在中国民用航空飞行学院公开招募。健康成人被纳入研究范围。本研究的入选标准如下：（1）中国民用航空飞行学院飞行技术专业或空中交通管理学院的本科生；（2）持有中国民用航空局CCAR-61-R4文件（含R5修正案）第D节15、16条规定的飞行学员执照，或有资格参加中国民用航空局CCAR-70TM-R1文件17条规定的民航空中交通管制基础培训证书考试的空管学员；

（3）符合中国民用航空局CCAR-67FS-R2文件（包括R3和R4修正案）17-19要求的身体条件；（4）自愿参与研究；（5）参与者自行评价身心健康。

Participants are publicly recruited from the CAFUC. The inclusion criteria for this study: (1) undergraduate students from the Aviation Technology major or the Air Traffic Controller College at the CAFUC; (2) participants holding a flight student license as specified in Section D of Articles 15 and 16 of the CAAC's CCAR-61-R4 document (including R5 amendments), or air traffic control students eligible to take the civil aviation air traffic control basic training certificate examination as specified in Article 17 of the CAAC's CCAR-70TM-R1 document; (3) participants who meet the physical

requirements specified in Articles 17-19 of the CAAC's CCAR-67FS-R2 document (including R3 and R4 amendments); (4) participants who voluntarily participate in the study; (5) participants who self-assess their physical and mental health.

3e. 被试排除条件 (Exclusion Criteria)

出现以下任一情况的被试将被排除：(1) 经历过仍对目前有显著负面影响的创伤事件； (2) 有自杀企图或非自杀性自伤(NSSI)的历史； (3) 在过去两年内接受过精神或心理治疗； (4) 在过去一年内有过自杀意念； (5) 正在接受心理咨询或治疗； (6) 被诊断出或有脑部或神经系统疾病史； (7) 在广泛性焦虑障碍(GAD)简易评估量表(GAD-7)中达到中度焦虑水平； (8) 在患者健康问卷9(PHQ-9)中达到中度抑郁水平。

Participants will be excluded if any of the following conditions apply: (1) having experienced a traumatic event that still has a significant negative impact on the present; (2) having a history of suicidal attempts or non-suicidal self-injury (NSSI); (3) having received mental or psychological treatment in the past two years; (4) having had suicidal ideation in the past year; (5) currently undergoing psychological counseling or treatment; (6) having been diagnosed with or having a history of brain or neurological disorders; (7) scoring at a moderate level of anxiety on the Generalized Anxiety Disorder (GAD) 7-item scale (GAD-7); (8) scoring at a moderate level of depression on the Patient Health Questionnaire-9 (PHQ-9).

被试排除评估在《知情同意书》中（见附件），被试在填写《知情同意书》时就已经完成了上述排除条件的排查。若出现上述任一排除条件，则被试将不被允许参加任何实验和签署《知情同意书》。

The exclusion criteria assessment is conducted in the *Informed Consent Form* (see Appendix). Participants complete the screening for the aforementioned exclusion criteria while filling out the *Informed Consent Form*. If any of the exclusion criteria are met, participants will not be permitted to participate in any experiments or sign the *Informed Consent Form*.

4. 研究设计、方法与程序(Research Design, Method, and Procedure)

所有受试者随机分为两组，A组（实验组）和B组（对照组）。在实验组中，参与者在显示设备上查看我们确定的材料。对照组查看常用的模拟外伤材料。

在实验开始前一周，所有参与者将被采集每日静息心率（RHR）数据。上述七天数据的平均值产生参与者的参考静息心率（RRHR），其被认为是参与者在平静状态下的心率值。

在实验当天，所有参与者被要求静坐20分钟，然后开始上述实验。在此期间，参与者被要求完成中国修订版的积极情绪和消极情绪量表（PANAS），并记录呼吸频率、心率、心率变异值等生理指标。实验结束后，要求参与者及时再次完成积极情绪和消极情绪量表。

All subjects were randomly divided into two groups, group A (experimental group) and group B (control group). In the experimental group, participants viewed the materials we determined on the display device. The control group checked the commonly used simulated trauma materials.

One week before the experiment, all participants will be collected daily resting heart rate (RHR) data. The average value of the above seven days' data generates the reference resting heart rate (RRHR) of the participants, which is considered to be the heart rate value of the participants in a calm state.

On the day of the experiment, all participants were asked to sit quietly for 20 minutes before starting the above experiment. During this period, participants were asked to complete the Chinese Revised positive and negative emotions scale (PANAS), and record physiological indicators such as respiratory rate, heart rate and heart rate variability. After the experiment, participants were asked to complete the positive and negative emotions scale in time again.

5. 实验仪器与样本采集（Experimental instruments and sample collection）

5a. 实验仪器（Experimental instruments）

☑ **使用以下国家认知与人格重点实验室公共设备 (Use public facilities)**

☐ 磁共振成像 fMRI	☐ 脑电 EEG	☐ 功能性近红外 fNIRS
☐ TMS	☐ tDCS	☑ 眼动 Eye tracking
☐ 生理多导记录仪 Peripheral physiology	☐ 虚拟现实 Virtual reality	☐ 睡眠记录 Polysomnography
☑ 行为 Behavior	☑ 其他 other	

☐ **使用非国家认知与人格重点实验室公共设备(Use non-public facilities)**

名称型号为_____

(请提交该设备的产品合格证、安全认证、使用说明等材料 submit security instructions)

5b. 研究是否涉及生物样本及相应信息(BIOLOGICAL SPECIMENS)

☐ 是 YES ☑ 否 NO

(人的生物样本指人的细胞、组织、器官、体液、菌群等和受精卵、胚胎、胎儿。涉及人类遗传资源的研究， 可能需向科技部申报审批，具体管理规定可查询 https://fuwu.most.gov.cn/html/xzxk/

Human biological specimens refer to the specimens including cell, tissue, organ, body fluid and bacteria colony, etc., as well as the specimens including fertilized egg, embryo and fetus. Studies involving human genetic resources may be subjected to approval by the Ministry of Science and Technology: https://fuwu.most.gov.cn/html/xzxk/)

5c. 生物样本或信息来源(Source)

（5c至5i选项仅5b选择是时需填写 Only the option 5b selecting Yes then fill in 5c to 5i）

☐ 自行采集样本 Collecting

☐ 使用已采集的样本 Use collected specimen (如适用科技部遗传资源采集审批，请提供审批决定书文号 Approval decision document number if applicable：_____)

☐ 样本保藏库，保藏库名称为 Specimen library, specify：_____(请提供科技部保藏审批决定书文号 Approval decision document number：_____)

☐ 使用已有生物样本信息，具体来源为 Existing biological specimen information ，specify：_____

5d. 生物样本是否涉及疾病 (Disease Involved)

☐ 否 NO

☐ 是， 疾病类型为 YES ，Disease type：

☐ 肿瘤 Tumor	☐ 脑血管 Blood vessel of brain	☐ 心血管 Cardiovascular	☐ 呼吸系统 Respiratory system
☐ 消化系统 Digestive system	☐ 内分泌、代谢及免疫 系统 Endocrine, metabolic and immune system	☐ 泌尿系统 Urinary system	☐ 神经系统 Nervous system
☐ 精神系统 Mental system	☐ 血液及造血系统 Blood and hematopoietic system	☐ 感染性疾病 Infectious diseases	☐ 五官 Ophthalmic and otorhinolaryngologic
☐ 皮肤 Dermatological	☐ 妇科 gynecological	☐ 儿科 Pediatric	☐ 环境与健康 Environment and health
☐ 遗传性疾病 Hereditary diseases	☐ 其他 Other：_____		

5e. 样本或信息用途(Use)

☐ 利用， 具体为 Utilize, specify：_____

☐ 暂无明确目的， 存储待用 No clear purpose currently

☐ 其他， 请说明 Other, specify：_____

国际合作 International cooperation：	☐ 是 YES	☐ 否 NO
样本出境 Specimens leave：	☐ 是 YES	☐ 否 NO
信息出境 Information leave：	☐ 是 YES	☐ 否 NO

5f. 样本采集场所、设施、设备和人员(Site, Facilities, Equipment and Personnel)

采集场所基本情况 Basic circumstances of the collection site	(比如：医院、具备资质的体检机构，等) (e.g. hospitals, qualified medical examination institutions, etc.)
主要设施、设备 Principal facilities	
人员(管理、实验操作、技术保障等人员) Personnel	

5g. 样本名称、采集量等(Name and Quantity)

名称 Name	单例数量 Quantity of a single example	例数 Number of examples	合计数量 Total quantity	单位/规格 Unit	备注 Remarks

注 Note ：

1. 名称 Name：全血 Blood、唾液 Saliva、尿液 Urine、头发 Hair、组织切片 Tissue slice 等。

5h. 样本采集时间地点 (Time and Location)

采集时间 Time ：_____(年/月/日) 至_____(年/月/日)

采集地点 Location：(如：x 省 x 市 x 县(区) x 镇(乡)街道(村)

_____

5i. 样本保存及销毁(Preservation and Destruction)

保存时限 Time range of preservation：_____(年/月/日) 至_____(年/月/日)

保存地点 Preservation location：_____

保存方式 Preservation method：_____

销毁时限 Destruction time ：_____(年/月/日) 之前

销毁方式 Destruction method：_____

研究伦理审核(Research Ethics Review)

1.风险与最小化风险措施(Risks and Measures to Minimize Risks)： 请根据申请课题的实际情况在每一项风险后面对可能存在风险的几率进行描述：非常常见(发生率 > 50%)；常见(发生率 > 25%；有可能(发生率介于 10-25%)；不常见(发生率介于 1- 10%)；罕见(发生率 < 1%)。

a. 心理风险(Psychological Risks)	
– 痛苦的情绪 Painful emotions	常见 Common
– 尴尬 Embarrassed	罕见 Rare
– 由于影响隐私而引起的情绪波动 Emotional fluctuations caused by privacy concerns	罕见 Rare
– 其他 Other	有可能 Possible
b. 社会风险(Social Risks)	
– 名誉或者地位受损Damage to reputation or status	罕见 Rare
– 对研究被试所代表的更大群体带来伤害(例如，歧视) Harm to the larger group represented by the research subjects (e.g.discrimination)	罕见 Rare
– 其他 Other	罕见 Rare
c. 经济风险(Economic Risks)	
– 收入的损失 Loss of income	罕见 Rare
– 失业或失去社会保障 Unemployment or loss of social security	罕见 Rare
– 其他 Other	罕见 Rare
d. 法律风险(Legal Risks)	

– 公开非法活动 Publicly disclose illegal activities	罕见 Rare
– 公开渎职 Public dereliction of duty	罕见 Rare
– 其他 Other	罕见 Rare
e. 生理风险(Physical Risks)	
– 生理疼痛 Physical pain	罕见 Rare
– 身体不舒适 Physical discomfort	有可能 Possible
– 身体伤害 Physical injury	罕见 Rare
– 其他 Other	罕见 Rare

2.受益(Benefits) 请描述被试参与此研究课题将会得到的直接与间接的受益。

免费的两年期心理健康情况随访与被试费用。具体权益以实验知情同意书为准

Free two-year mental health follow-up and participant costs. Specific rights are as outlined in the informed consent document.

3.被试隐私保护(Participants Privacy Protection)

以实验知情同意书为准。

The contents shall be governed by the informed consent form for the experiment.

4.数据保密(Confidentiality of the Data)

所有被试的数据经过完全保密，并在研究、专著等任何面向不特定人的发表中完全按照《中华人民共和国个人信息保护法》的规定处理为不可识别任何特定人的信息（即不可识别到特定的人）。

Data of all participants are kept strictly confidential and in any publication, including research and monographs, that is accessible to unspecified individuals, the data are processed in full compliance with *The provisions of the Personal Information Protection Law of the People's Republic of China* to ensure that the information cannot be traced back to any specific individual (i.e., cannot be traced back to specific individuals).

5.被试知情声明(Participants Consent Statement)

（请附被试知情声明书范本。并简述被试知情情况）（Please attach a sample Informed Consent Form (ICF) for participants. Additionally, briefly describe the informed consent process for participants）

被试经过知情同意书的完全说明，包括其可以随时退出、撤销使用、不可识别等所有依照心理学研究惯例的被试知情说明情况。

Participants were fully informed through the informed consent document, including their right to withdraw at any time, revoke their consent, and maintain their anonymity, in accordance with standard practices in psychological research.

6. 研究负责人保证书(Certification of Principal Investigator)

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，并遵守国家和集团伦理委员会的相关规定。

The above information is true. If approved, I will strictly follow the provided plan for research and comply with the relevant regulations of the National and Group IRB.

签名(Signature)： 王新 **日期(Date)：** 24/3/13

审批意见及结果

1. 伦理委员会审核意见(Review Opinions of the IRB)

集团研究伦理委员会于2022年3月15日二届三次全委会上审议了本研究。委员会认为，本研究风险与获益平衡相当，研究目的明确，具有操作性；研究人员综合水平符合要求，研究伦理达标。准许该研究通过。

The Group Research Institutional Review Board reviewed this study at its Second Session, Third Plenary Meeting on March 15, 2023. The board determined that the study's risks and benefits are well-balanced, with clear objectives and operational feasibility. Additionally, the researchers meet the required standards in both comprehensive capabilities and ethical standards. The study was approved.

同意（Agree） ☑ 不同意（Disagree） ☐

以下签名确认本委员会已经考察了研究申请人的科研水平和所提科研项目的科研价值，并同意该研究申请人主持此项研究工作。
（**The following signature confirms that our committee has examined the research level of the research applicant and the research value of the proposed research project, and agrees that the research applicant will preside over this research work.**）

董怡然 王瑞珍

2022.03.15

伦理委员会评审专家签名 (Signatures of Committee Member)	日期 (Date)

伦理委员会主席本次表决被回避，由副主席行使主席权利。
The chairman of the institutional review board was recused from this vote, and the vice-chairman exercised the chairman's authority.

王瑞珍

2022.03.15

伦理委员会主席签名 (Signature of Committee Chair)	日期 (Date)