CAM-SU GRC
剑桥-苏大基因组资源中心

伦理审查

本文件常更新，请到官网下载最新版本

AP 常见问题

要求：

1，中心学生和中心课题组合作学生开展实验前必须申请 AP

2，持已通过审核的 AP 进行购买小鼠和开展实验

3，分配笼位依据 AP 中笼位数量

申请 AP 前提：

1，注册中心官网账号，已加入课题组

2，个人中心处上传《江苏省实验动物专业技能培训记录卡》（后面简称动物上岗证）

常见问题：

问：没有动物上岗证怎么办？

答：每年 7/8 月或者 11/12 月有考试安排，详情关注苏州大学动物中心官网，申请人必须有上岗证。

审核中出现的高频问题（表格内为本中心审核实际评审截选）

1	申请人未上传江苏省实验动物专业技能培训记录卡
2	错别字，英文书写错误等，漏填信息
3	项目名称和实验研究目的不一致
4	所填写小鼠信息未全部写明用途
5	小鼠信息不全
6	小鼠每笼 5 只，笼位数和动物数量不匹配
7	使用小鼠品系，数量的依据，分组的依据，小鼠数量是如何确定
8	小鼠实验重复数太少：该动物实验周期很短，几周即可完成，考虑增加重复实验
9	前后描述小鼠数量不一致，数量夸大
10	动物使用计划与项目周期不符
11	具体采集的样本？
12	具体研究的哪一类肿瘤模型
13	脱颈处死的理由
14	疼痛分级为 D，应描述镇痛缓解方式
15	请确认安乐死方式，脱颈无必要性时不推荐使用；另补充出现非正常情况时的人道终点判定标准

伦理审查

伦理审查　ethical review

按照实验动物福利伦理的原则和标准，对使用实验动物的必要性、合理性和规范性进行的专门检查和审定。

GB/T 35892-2018实验动物 福利伦理审查指南

5 审查原则

5.1 必要性原则

实验动物的饲养、使用和任何伤害性的实验项目应有充分的科学意义和必须实施的理由为前提。禁止无意义滥养、滥用、滥杀实验动物。禁止无意义的重复性实验。

5.2 保护原则

对确有必要进行的项目，应遵守3R原则，对实验动物给予人道的保护。在不影响项目实验结果的科学性的情况下，尽可能采取替代方法、减少不必要的动物数量、降低动物伤害使用频率和危害程度。

5.3 福利原则

尽可能保证善待实验动物。实验动物生存期间包括运输中尽可能多地享有动物的五项福利自由，保障实验动物的生活自然及健康和快乐。各类实验动物管理和处置，要符合该类实验动物规范的操作技术规程。防止或减少动物不必要的应激、痛苦和伤害，采取痛苦最少的方法处置动物。

5.4 伦理原则

尊重动物生命和权益，遵守人类社会公德。制止针对动物的野蛮或不人道的行为；实验动物项目的目的、实验方法、处置手段应符合人类公认的道德伦理价值观和国际惯例。实验动物项目应保证从业人员和公共环境的安全。

CAM-SU GRC
劍桥-苏大基因组资源中心

AP

- ✓Animal protocol（实验动物使用计划）
- ✓任何动物实验开展前，必须向IACUC提交AP，主要说明使用实验动物的必须性，使用数量、计划的合理性、对保障动物福利方面的措施
- ✓投稿需要

IACUC: Institutional Animal Care and Use Committee

研究机构动物使用与管理委员会

负责审查动物实验，保障动物福利

动物福利

- ✓ 生理福利，即无饥渴之忧虑
- ✓ 环境福利，也就是要让动物有适当的居所
- ✓ 卫生福利，主要是减少动物的伤病
- ✓ 行为福利，应保证动物表达天性的自由
- ✓ 心理福利，即减少动物恐惧和焦虑的心情

3R原则

- ✓ Reduction（减少）
- ✓ Replacement（替代）
- ✓ Refinement（优化）

CAM-SU GRC
剑桥-苏大基因组资源中心

IACUC

剑桥–苏大基因组资源中心实验动物使用和管理委员会（CAM–SU IACUC）是依据实验动物相关的法规、管理规定及动物福利与伦理规则成立的，负责监督和评估本中心开展的实验动物相关项目是否符合伦理道德的规范要求。

现任CAM–SU IACUC成员包括：

主席：徐璎

兽医：王婧、王晨娟

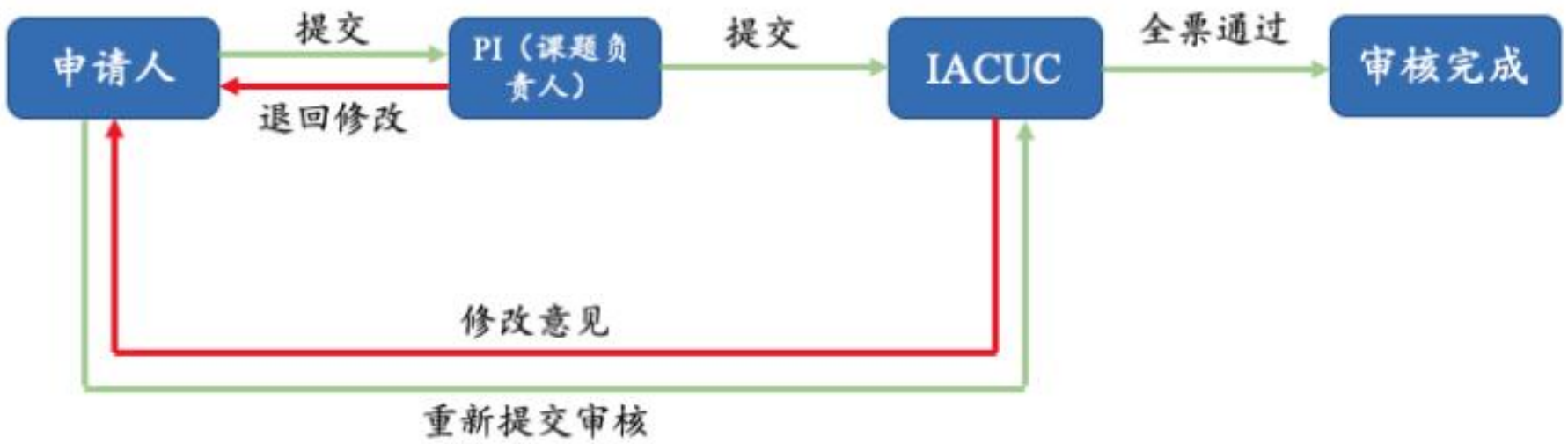
社会人士：邓刚、郭连香、袁凯

研究者：丁宁、何伟奇、贾志浩、刘志玮、龙乔明、潘德京、任文燕、王涛、张文胜、张勇、周飞

https://www.cam-su.org/cms/337951.html

AP申请审核流程

在线提交-审核

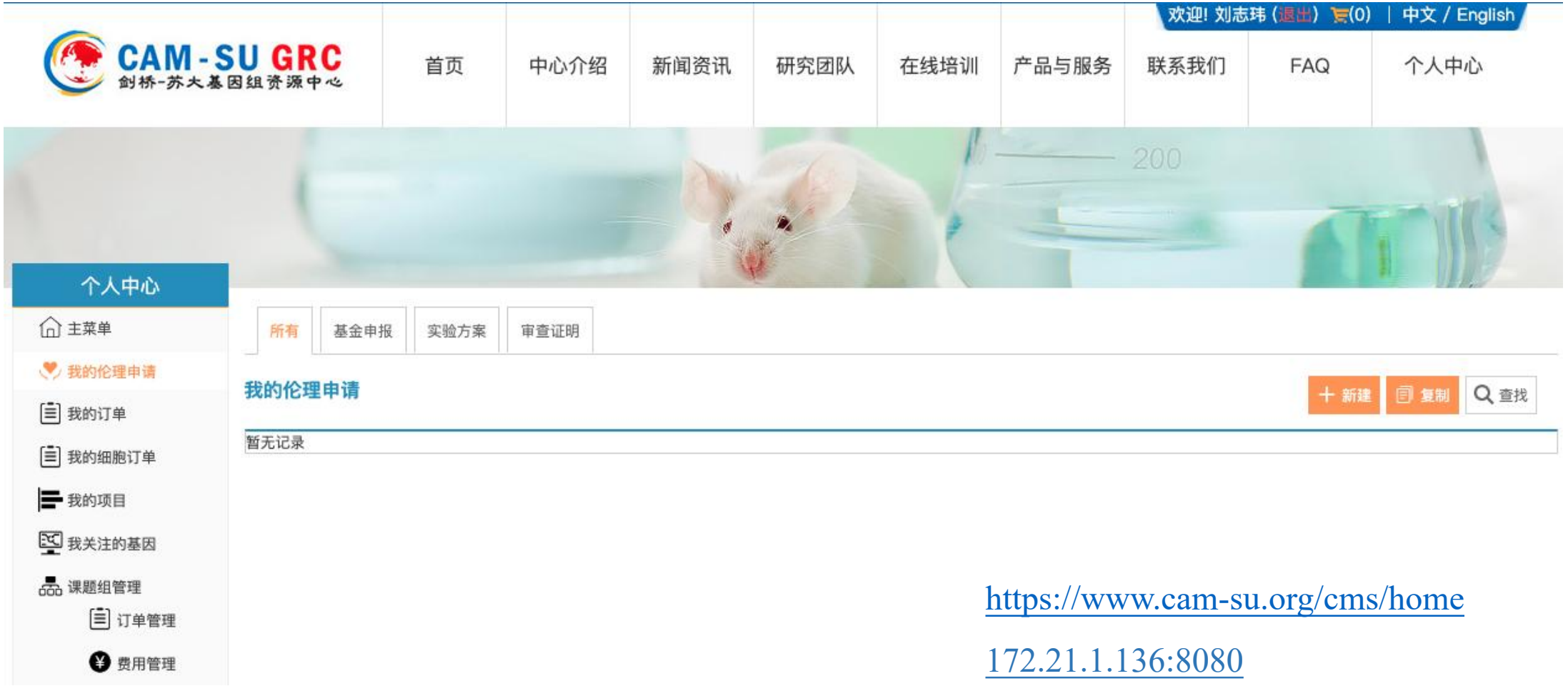


注意：伦理申请的 IACUC 审查阶段仅限两轮，如第二轮依然不能审核通过，需重新提交申请，请课题负责人对提交的申请书把关。

审查项目，包括但不限于以下各方面：

- 开展实验的人员是否全部列在批准后AP中。
- 实验室开展的实验是否全部列在批准后AP中。
- 实验室使用的麻醉剂，镇痛药，止痛药，抗生素或者其他用药是否全部在post-approval animal protocol中列明，是否与post-approval animal protocol中所列相同，是否按照post-approval animal protocol所写方法进行使用。
- 是否实行或者是否记录post-approval animal protocol中所列的促进动物福利的措施。
- 存活性手术是否在无菌条件下进行。
- 安乐死方法与post-approval animal protocol所列是否一致或是否采取安乐死的方法。
- 实验室人员是否有足够的训练来开展post-approval animal protocol中所列的相关实验。
- 动物护理、术后护理的文档是否完整。
- 实验环境对人和/或动物是否安全。
- 是否使用过期物品（如：药物，试验试剂，缝线，灭菌用品等）。
- 正在使用的设备是否准确，有误差是否及时校准。

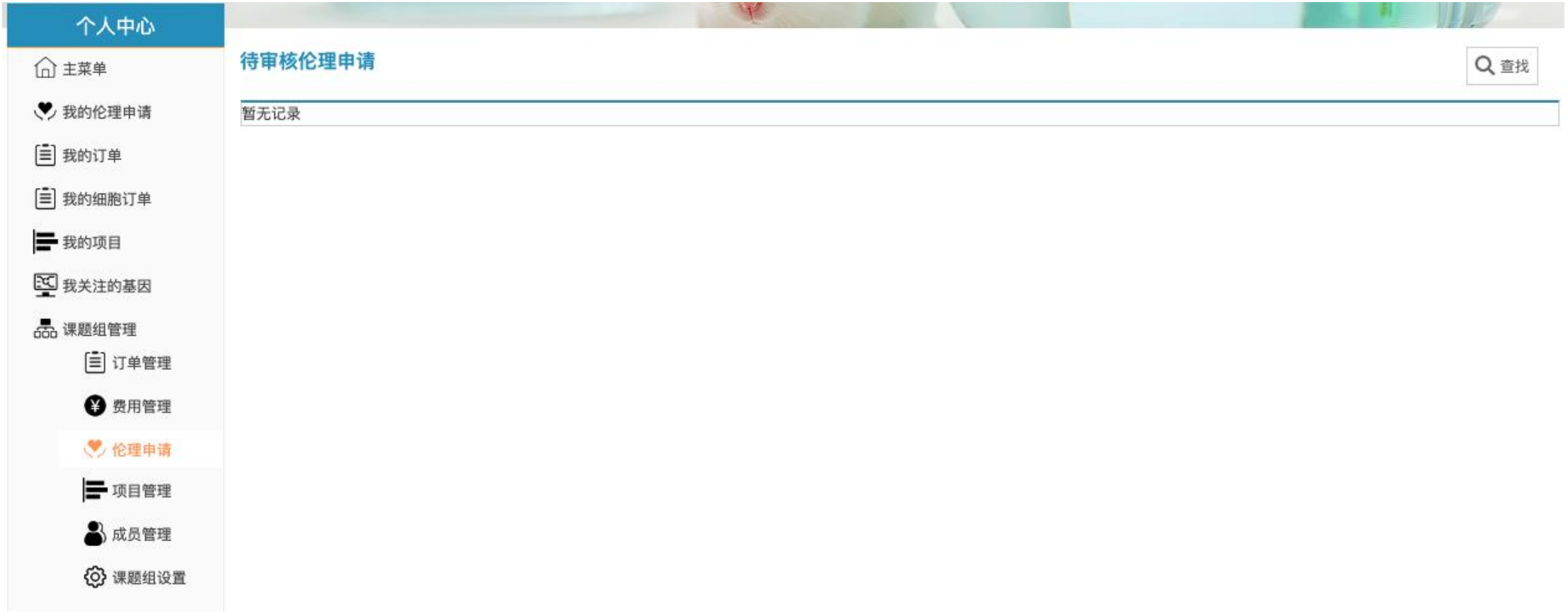
AP申请入口



https://www.cam-su.org/cms/home

172.21.1.136:8080

AP课题组审核入口


个人中心
主菜单
我的伦理申请
我的订单
我的细胞订单
我的项目
我关注的基因
课题组管理
订单管理
费用管理
伦理申请
项目管理
成员管理
课题组设置
待审核伦理申请
查找
暂无记录

IACUC审核入口

thical/control/main

l/control/main

AP申请书

https://www.cam-su.org/

审核结果	审核备注	审核明细
修改后重新提交审核	-	2: 用鼠计划与项目年限不符 9: 实验设计部分描述过于简单，未涉及所有引用的SOP
审核通过	-	-
审核通过	-	-
审核通过	-	-
修改后重新提交审核	实验计划描述稍显简单，建议增加说明，如动物在代谢笼观察时间，补充取样操作相关流程计划。	-
修改后重新提交审核	-	1.4: 时长为3年
修改后重新提交审核	Project title needs revision。 2. 品系名称gpr45 tm1d;Agrp-cre命名有误。tm1d=tm1c+Cre。 6. 各品系小鼠数量与第2部分有差异，同时应该也需要Gpr45 tm1c小鼠	-

审核结果	审核备注	审核明细
修改后重新提交审核	-	1.1: PI需选择，信息缺失 1.2: 列入其他研究人员 1.4: 1.核对选项 2.经费号最好标注来源 3. 一般按3年申请，是否修改起止时间 2: 没有使用的动物信息及每年的使用计划 6: 需描述更清晰，如48只全组织取样鼠是哪些组的 7: 使用的药物不明确，是否有危害需要补充 9: 实验中动物数量和统计说明中不符
修改后重新提交审核	1）需在第2部分描述小鼠使用总量及年度计划，另外建议按比例超额准备小鼠并设置重复实验； 2）第6和第9部分关于小鼠数量的描述不吻合？ 3）如果没有hazardous agent，不用填写第7部分	-

审核结果	审核备注	审核明细
修改后重新提交审核	请认真核对数量、安乐死部分内容	6: 统计分析与动物使用计划依然无法对应，请重新提供测算数据 13: 安乐死方法再核对，选项与描述不符；脱颈处死需要论述必要性，非描述方法
修改后重新提交审核	开始时间预计为2021年，不符合先伦理审查再开展动物实验的要求。计划动物数量仍不符，请再次核对。 第9点动物实验的计划和描述过于简单，请补充。特别是补充动物安乐死等内容，并请与前后文一致。	-
修改后重新提交审核	对其他评审的审核请认真对待修改	-
修改后重新提交审核	请仔细核对小鼠数量，以及安乐死这部分内容。	6: 这部分小鼠数目的描述还是与上面的不符合，请核对清楚 13: perfusion under anesthesia没有选，下面也没有列举具体情况
修改后重新提交审核	核对小鼠使用数量	-
修改后重新提交审核	1. 动物数量的统计（第6部分）与需求（第2部分）的数据不符合; 2. 安乐死描述提到perfusion under anesthesia但并未勾选对应选项。	-
修改后重新提交审核	仔细核对小鼠使用数量	-

CAM-SU GRC
劍桥-苏大基因组资源中心

CAM-SU GRC 因组资源中心

1. Administrative data.

"Other investigators" refers to all personnel involved in the experiment.

If you don't belong to CAM-SU GRC, you should cooperate with a PI of CAM-SU GRC who should take responsibility for your experiment. And, "co-principal investigator" refers to your own tutor.

Principal investigator (PI in CAM-SU)	PI及Co-PI信息		
E-mail			
Office phone		**Cell phone**	
Co-principal investigator			
E-mail			
Office phone		**Cell phone**	
Other investigators			
E-mail	需列出所有参与人员，	人员变动需提交修订	
Office phone			
Cell phone			
Project title	项目名称		
Funding origin (No.)	基金号		
Estimated start date		**Estimated end date**	不超过3年

Please check all that apply		New		3 year rewrite		Transgenic creation
		Breeding/maintenance		Experimental		Knockout creation
		Survival surgery		Non-survival surgery		Behavior studies
		BrdU labeling		embryo collection		Source of tissues
		Immunization		Monoclonal antibody production		Polyclonal antibody production
		Anesthetize and release (blood collection)		Tumor induction or implantation		Other, please specify below:
	AP基本情况，需要涉及到的实验操作					

2. Animal requirements.

(If more than one strain is required, please add the table below for each strain)

Strain/line		
Gender		
Age range	使用的动物的属性	
weight range		
Other requirement		
	Number of animals to be used	Number of cages to be used
Year 1		
Year 2	3年的动物、	笼位使用计划
Year 3		
Total		

3. Objective/Hypothesis

Briefly describe in non-technical terms the scientific aims of this project. This is where you will describe the `what' and `why' of your protocol.

Justify the project in terms of its potential value in advancing scientific knowledge and/or the benefits of the study to human and/or animal health. Provide sufficient information to indicate that the potential new knowledge from the project justifies the use of animals, improvement of animal management or production.

Jargon should be avoided or explicitly explained (please define all acronyms).

论述实验的目的，项目的意义
不是简单的描述要做什么，而是为什么要这样做

4. Rationale for animal use.

Please list the alternative to animal use and potential harmful procedures, such as less-invasive procedures, other species, isolated organ preparation, cell or tissue culture, or computer simulation.

描述为什么要用动物做实验，为什么是不可替代的使用

5. Justify the appropriateness of the species/strain selected.

Please indicate what the advantages of the species/strain you choose are, Such as, easy to model, or particular genetic background, or proven susceptibility to particular induction, or expression of particular gene, etc.

描述为什么要使用何种动物，为什么选择用某种品系来进行

✧ **6. Statistical analysis.** (The asterisk indicates this is the focus of review. The same below) Insufficient justification of animal numbers will result in protocol rejection. Include the total numbers of animals used in each experiment and over a 3-year period. Identify any statistical analysis used to demonstrate why this number of animals is necessary for this study.

提供统计学上的证明，说明使用的动物数量是合理的。此处数量应与2 Animal requirements对应

非常重要，超过10%的数量变动会需要重大修改

7. Hazardous agents.

Check if hazardous chemicals, toxins, biologicals and radioactive agents are to be used

(Hazardous agents include, but are not limited to: infectious agents including bacterial, chlamydiae, fungi, rickettsias, viruses, parasites, prions, human blood, body fluids, tissues or cell cultures, recombinant DNA and the creation (but not acquisition) of transgenic animals, mutagenic or teratogenic substances; sterilant or anesthetic gasses. Radioactive agents include: x-rays, lasers, sealed sources and radioisotopes.)

If yes, please attach a separate sop on handling substances, animals and equipment.

	Yes		No

Hazardous agents Category					
		Biological/infectious agents			Recombinant DNA
		Hazardous chemicals			Radioisotopes
		Select agents			
		Name of agent(s)			

明确实验过程中是否涉及有害物质，有的需要单独提供涉及这些操作的SOP

CAM-SU GRC
劍桥-苏大基因组资源中心

Where will procedures be performed?

In the lab and the conventional side of animal facility

Where will animals be housed?

Crossing and breeding in the conventional side of animal facility

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8. Will you use CAM-SU GRC SOPs?

Check and attach CAM-SU GRC SOPs (\\172.21.1.188\Share\03 CAM-SU Animal Protocol)

List the Number and title of CAM-SU GRC SOPs

引用所有需要用到的SOP

✧ 9. Description of experimental design and animal procedures.

Describe the experimental design as it relates to the number of animals indicated in **No. 2. Animal requirements**. Specify animal procedures including inoculations (sites, substances, dosages and schedules), blood withdrawals (volume, frequency and withdrawal sites), surgical procedures (provide details on separate form), radiation (dosage and schedule), tail biopsies. Euthanasia criteria (tumor size, percentage body weight gain or loss, inability to drink, clinical symptomatology or signs of toxicity) must be specified when administration of tumor cells, biologicals, infectious agents, radiation of toxic chemicals are expected to cause significant symptomatology or are potentially lethal. Use of death as an endpoint must be scientifically justified.

实验设计的描述，包括：
动物数量
试剂剂量
采血量，频率，采血部位
人道终点。。。

10. What is the expected duration of survival after expression of the phenotype?

出现表型后的实验终点

重点审查部分
疼痛级别

✧ 11. Pain or Distress Category.

A generally acceptable method of determining whether or not a procedure would be painful is to consider whether it is considered a painful procedure in man. If it is, then appropriate anesthesia or analgesia should be used. CAM-SU GRC currently employs three Pain and Distress Categories C, D, and E (corresponding to the USDA reportable pain categories). Please indicate the type of pain to be experienced with this research.

	PAIN CATEGORY **C**		PAIN CATEGORY **D**		PAIN CATEGORY **E**

For E, (must be scientifically justified) please cite references below:

Definitions:

Category C: Includes only procedures that are considered to produce minimal, transient, or no pain or distress in animals when performed by a competent individual. The definition of USDA category C also emphasizes that protocols involve no more than momentary or slight pain or distress and no use of pain-relieving drugs. Examples include: breeding protocols, injections of material in amounts that will not cause adverse reactions by the following routes: IV, SC, IM, IP; gavages, restraint, tail cuts.

Category D: Includes procedures that have the potential to produce pain or distress in animals, but which are performed using appropriate and adequate anesthetics, analgesics, or tranquilizers to alleviate the pain or distress. Examples include: retro-orbital bleeds, cannulation or catherization of blood vessels or body cavities under anesthesia, surgical procedures under anesthesia such as biopsies, hepatectomies, stroke, spinal injuries with post-op analgesia.

Category E: Includes potentially painful or distressing procedures that are performed without appropriate and adequate anesthesia, analgesia, or tranquilizers; or are not followed with appropriate measures to alleviate pain or distress; or are not amenable to relief by therapeutic measures. Provide written justification of your requirements. E protocols require the prior review and approval of the full IACUC members before they are initiated. Examples: death as an endpoint studies.

✧ 12. Release of pain or distress.

Will the animals experience pain or distress in association with the phenotype expressed or proposed procedures? What are your plans to avoid or alleviate pain? If your animal protocol involves major survival surgery procedure, please state the pain-releasing drug (component, dose, administration method and time-interval) used post-surgery.

重点审查部分
缓解疼痛的有效方式

13. Method of health treatment and euthanasia 安乐死方式选择

	Cervical dislocation*		Exsanguinations with anesthesia		Other***
	Decapitation*		Perfusion under anesthesia		
	Anesthesia overdose**		**CO_2 (Recommended)**		

***Cervical dislocation and decapitation are not recommended and if performed must be justified by scientific necessity. Please detail it.**

非建议方式需要详细描述理由

****Specify agent, dose, frequency and administration route:**

过量麻醉致死方式需要描述使用的麻醉剂类型、用量　注意：有的麻醉剂已禁止使用

*****Specify below:**

Please list the health treatment and possible euthanasia in case of the possible animal sickness and failure of protocols.

Retain Carcass for subsequent experiments? 保留进行后续实验？

	Yes, 4℃		Yes, -20℃		No

14. Training.

All research personnel must be appropriately qualified to perform their work with animals.
Qualifications should be in the following areas:

*the basic biology of each species of animals used.

*proper handling of species used.

*adequate familiarity with experimental protocol and techniques as well as pre- and post-procedural care including aseptic techniques.

Training Certifications:

Researchers, including facility staff, have the knowledge and skills enumerated above.
Trained animal technicians will perform all breeding and/or experimental procedures.
List all the person training record of CAM-SU GRC/other facility on this ANIMAL PROTOCOL:

上岗证、培训记录

常见的问题

CAM-SU-AP#: YZ-2021-1

1. Administrative data.

"Other investigators" refers to all personnel involved in the experiment.

If you don't belong to CAM-SU GRC, you should cooperate with a PI of CAM-SU GRC who should take responsibility for your experiment. And, "co-principal investigator" refers to your own tutor.

Principal investigator (PI in CAM-SU)	**Yong Zhang**		
E-mail	**yong.zhang@suda.edu.cn**		
Office phone		**Cell phone**	**86-13621638489**
Co-principal investigator			
E-mail			
Office phone		**Cell phone**	
Other investigators			
E-mail			
Office phone			
Cell phone			

参与人信息缺失

Project title	**The mechanism and function of Circadian Rhythms**		
Funding origin (No.)	NSFC 31630091, 31230049, 2018YFA0801100		
Estimated start date	2020.01	**Estimated end date**	2023.12

AP执行期超三年

Project title	**Study the function of disease-related human new genes**		
Funding origin (No.)			
Estimated start date	2021-1-1	**Estimated end date**	2023-12-31

没有基金号

选项矛盾

Please check all that apply	√	New	√	3 year rewrite	√	Transgenic creation
	√	Breeding/maintenance	√	Experimental		Knockout creation
	√	Survival surgery	√	Non-survival surgery	√	Behavior studies
	√	BrdU labeling	√	embryo collection	√	Source of tissues
		Immunization		Monoclonal antibody production		Polyclonal antibody production
	√	Anesthetize and release (blood collection)		Tumor induction or implantation		Other, please specify below:

✧ **6. Statistical analysis.** (The asterisk indicates this is the focus of review. The same below) Insufficient justification of animal numbers will result in protocol rejection. Include the total numbers of animals used in each experiment and over a 3-year period. Identify any statistical analysis used to demonstrate why this number of animals is necessary for this study.

Histological and expression analysis:
100 mice x 1 transgenic lines x 1 founders = 100
50 mice x 1 transgenic lines x 1 founders = 50 (for MEF cells isolation)
60 mice x 1 wild type lines x 1 founders = 60
Total number of mice used is 120.

只有数量，没有测算依据

✧ 11. Pain or Distress Category.

A generally acceptable method of determining whether or not a procedure would be painful is to consider whether it is considered a painful procedure in man. If it is, then appropriate anesthesia or analgesia should be used. CAM-SU GRC currently employs three Pain and Distress Categories C, D, and E (corresponding to the USDA reportable pain categories). Please indicate the type of pain to be experienced with this research.

✓	PAIN CATEGORY **C**

✓	PAIN CATEGORY **D**

✓	PAIN CATEGORY **E**

For E, (must be scientifically justified) please cite references below:

Mice will be sacrificed by CO2 and some of the tissues will be collected for histological evaluation (immunohistochemistry or immunostaining).

E类疼痛没有描述、依据

7. Hazardous agents.

Check if hazardous chemicals, toxins, biologicals and radioactive agents are to be used

(Hazardous agents include, but are not limited to: infectious agents including bacterial, chlamydiae, fungi, rickettsias, viruses, parasites, prions, human blood, body fluids, tissues or cell cultures, recombinant DNA and the creation (but not acquisition) of transgenic animals, mutagenic or teratogenic substances; sterilant or anesthetic gasses. Radioactive agents include: x-rays, lasers, sealed sources and radioisotopes.)

If yes, please attach a separate sop on handling substances, animals and equipment.

	Yes	✓	No

Hazardous agents Category				
		Biological/infectious agents		Recombinant DNA
		Hazardous chemicals		Radioisotopes
		Select agents		
		Name of agent(s)		

Mating: Different mice will be crossed to generate transgene mice models.
Mice Sacrifice: After sub-lethal irradiation to mice and their MEF cells, survival rate shall be evaluated to mice, and MEF cells shall be measured in cell biology.

放射处理没有说明