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## 方案撰写建议与指南 IACUC Application Writing Tips & Guidance

### 撰写建议 Tips for Writing your IACUC Protocol

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### 撰写建议 Tips for Writing Your IACUC Protocol

1. 使用通俗语言总结你的方案, 想象成将你的方案描述给学生或家人朋友。Provide a summary in lay language of the project – imagine you were describing your research to a classroom of students or your relatives at a family reunion.
2. 充分考虑“3R”原则, 以及减少不必要的实验重复。Consider the “Three Rs” and unnecessary duplication:
  - *代替 Replacement*: Are there any alternatives to the use of live animals? If yes, you must provide a scientific justification for not using them.
  - *减少 Reduction*: Is the number of animals requested in the protocol adequate to achieve scientifically-valid results? How did you determine that the number is adequate but not unnecessarily large?
  - *优化 Refinement*: If procedures are likely to cause pain or distress, what will be done to minimize it?



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- 如果已有相关研究发表, 请详述本方案的特别之处。 If similar projects or experiments are found in the scientific literature, describe what it is that makes this project unique.
  - 3. 确认所有参与人员列入到方案中。 Be sure all study team members are listed
  - 4. 提供选择相应动物品系的科学解释。如果需要多种动物品系, 请解释理由。 Provide justification for why a particular species was chosen and describe any strain or breed characteristics. If multiple strains or breeds of a species is needed, explain why.
  - 5. 陈述你的假设和实验设计, 提供以下信息 State your hypothesis and design experiments to test it. Be sure to provide:
    - 所有实验的科学理由 Scientific rationale for all experiments
    - 动物实验流程的时间线 Timeline of procedures that will be performed on the animals
    - 研究小组的术后监测计划 Post-procedural monitoring performed by the study team (not ASC)
    - 实验终点( 什么节点动物结束实验或被安乐死。 ) Experimental Endpoints (point at which the live-animal portion of the experiment is complete and animal is euthanized)
    - 人道终点 ( 动物在实验结束前实施安乐死的标准 ) Humane Endpoints (criteria that are used to euthanize an animal earlier than the expected experimental endpoint)



6. 根据动物品系,列出动物数量,并给出之所以使用这些数量的计算原理跟理由。List the animal numbers, specifying the different groups and # per group and provide justification for how the number of animals was determined
7. 提供每一步操作动物的细节说明(包括非手术以及手术操作)。Provide details of all procedures (both non-surgical and surgical) that will be performed on the animals.
8. 请在方案中讨论动物操作或模型建立过程中动物可能出现的任何异常状况、副作用等引发的任何临床症状。描述动物在经历痛苦、不安、压力紧张、不适情况时如何对动物做到相应的观测。并需要列出动物撤出实验方案以及安乐死的标准。Discuss in detail any clinical signs and symptoms, possible side effects and adverse effects associated with either the disease model being studied or the procedures to be performed. Describe how animals will be monitored and treated for pain, distress and discomfort, and list the criteria that will be used for determining that animals must be removed from the study and euthanized.
9. 列出所有用于动物的试剂和药品信息。List all agents and drugs that will be administered to live animals

注意:所列出的物品要在相应操作中描述用途。NOTE: All items listed in this tab should also be referenced in other relevant sections of the protocol (Experimental Design, surgical/non-surgical procedures, pain management, etc.).



10. 描述实验结束后动物的安乐死方法。动物尸体处理前必须确认死亡。此外，系统所 IACUC 推荐二氧化碳过量麻醉后使用二次物理法确认死亡（如，脱颈），详情请查看 IACUC 安乐死指南。 Describe how animals will be euthanized at the end of the study Death must be confirmed in all animals prior to carcass disposal; in addition, ISM IACUC Policy requires that all rodents euthanized via CO2 overdose undergo a secondary physical method of euthanasia (e.g., dislocation) prior to disposal to prevent unintended recovery. See the IACUC Policy on Euthanasia for more information.

#### 特殊操作细节描述 Additional Details about Specific Procedures

As you enter information into the protocol tabs in RMS, you may be prompted for additional details, depending on your specific experiments and proposed procedures. The following list includes items that the IACUC will require specific details about:

- **项目周期说明 Project Continuation:** 项目进行报告；当一个三年的方案需要更新时，IACUC 需要先审核此方案三年内的进展情况。Essentially a progress report; Required ONLY if you are writing a three-year de-novo review of an ongoing, project previously approved by the IACUC



- **繁殖方案 Breeding:** 当动物品系需要保种,生产的动物用于后续实验时需要提交繁殖方案。 Required if a breeding colony of animals will be maintained to supply offspring for research purposes (usually genetically-modified rodents).
- **长时间动物保定限制说明 Prolonged Restraint:** 当动物保定时间过长时,需要提供说明。详情参见 IACUC 指南。 Required if animals will be restrained for more than very short periods of time while awake. See the IACUC Policy on Animal Restraint.
- **麻醉制剂的使用说明 Use of Paralytic Agents:** 当项目中使用到神经肌肉阻断试剂作为麻醉药品时,需要提供说明。 Required for the use of neuromuscular blocking agents in anesthetized animals.
- **多重存活手术 Multiple Survival Surgery:** 当单个动物需要操作多重存活手术时,需要提供说明,详情参见 IACUC 指南。 Required when individual animals will recover from more than one surgical procedure. Review the IACUC Surgery Policy and Guidelines.
- **制备抗体 Antibody Production:** 使用活体动物制备单克隆或多克隆抗体时,需要提供说明 Required for the production of monoclonal or polyclonal antibodies in live animals.
- **研究员自行照料动物 Researcher-Maintained Animals:** 如果项目组自行照料动物,需要提供说明 Required if laboratory staff will provide care and husbandry of the animals either within ASC-operated housing facilities or outside of vivarium housing.



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- **特殊饲养 Housing Exception:** 对于动物将在动物中心以外的环境饲养、实验的情况, 需要提供说明 Required if animals will be kept outside of ASC-maintained vivarium housing space for more than 12 hours.
  - **其他饲养方式 Variations in Husbandry/Housing:** 对于与动物中心提供的饲养标准不同的, 例如网格笼具、饮水饮食限制、异于中心标准的饲养光照、温湿度等。Required for all variations to standard ASC-provided husbandry and care. Examples include use of wire-bottom caging, food or water restriction or additions, variations in standard light cycles, temperature or humidity, etc.

注意 Notes:

- 如果方案内试剂使用危险物质, 请提供安全使用此类危险物质的说明材料, 例如动物设施风险交流表、材料安全使用单, 标准操作规范等。If your research involves Hazardous Agents, you may be required to submit various documents pertaining to their safe use, such as Animal Room Hazard Communication Forms (door signs), Material Safety Data Sheets (MSDS) and Standard Operating Procedures (SOPs) for the handling of hazardous substances.  
请联系职业安全健康管理委员会了解详情。Contact EH&S for assistance - for more information.
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## 签字要求 Required Signatures

方案中必须有以下签名 The following are required for an IACUC protocol:

首席研究员可通过方案提交时系统的电子签名完成 Signature from the Principal

Investigator must be provided, ideally via electronically signing the protocol in

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## 其他管理审查 Other Regulatory Reviews

操作动物前，方案审核中需要其他管理委员会的审批包括 Additional regulatory committee reviews and institutional approvals may be required before the IACUC can release approval to work with live animals:

- 机构内的生物安全委员会须审批 Institutional Biosafety Committee (IBC) review is required for the use of
  - 方案中若涉及重组 DNA 的使用 Recombinant DNA
  - 物质使用风险 Risk Group Agents/Select Agents
  - 生物安全 Biological hazards
  - 人源化或灵长类组织器官的使用 Use of any materials of human or non-human primate origin
- 职业健康安全委员会审查。 Environmental Health and Safety (EH&S) has oversight responsibility for all safety-related issues in research. Please refer to EH&S laboratory and research guidance for more information.