**Non-Human Subject Research Proposal Template**

**PRINCIPAL INVESTIGATOR PAGE**

**Principal Investigator Information**

**First name:**

**Middle initial:**

**Last name:**

**Email address:**

**Phone number:**

**Department:**

**Status:**

**Will you be working with additional investigators? If yes, please complete the Sub-Investigator information.**

**SUB-INVESTIGATORS PAGE**

**Sub-investigator Information**

**First name:**

**Middle initial:**

**Last name:**

**Email address:**

**Phone number:**

**Status:**

**Department:**

**Add another sub-investigator?**

**PROJECT INFORMATION**

**Project Information**

**Study Title:**

**Abstract:**

**List of Abbreviations:**

Include commonly used abbreviations and acronyms.

**Problem Identification/Background**/**Literature review with references/Research Question:**

The introduction should open with remarks stating this document is a research protocol and that the described study will be conducted in compliance with the following as applicable: institutional research requirements; Common rule; FDA; Good Clinical Practices (GCP) International Conference on Harmonization (ICH) Guidelines (E6) for GCPs standards. You must be familiar with the regulations governing this research.

Emphasize that this project will produce new and generalizable knowledge (research).

Provide and summarize published (or available unpublished) data in the literature to build a rationale for the research question(s), study objectives, and research design. If none is available, include a statement that there is no available research data to date on the intervention being investigated.

Use your program's required citation style.

This section must provide a justification for the conduct of this study based on existing knowledge and the research question.

Identify the population of interest. You may include a summary of epidemiological data, if relevant.

**Study Objectives/Aim/Hypothesis:**

In a general fashion, summarize the purpose, aim, or objective of the study.

**Primary Objective/Aim/Goal/Hypothesis**

Select the appropriate term (objective/aim/goal/hypothesis) for your research area and be consistent throughout the proposal. Include the details of the study’s primary objective (which is the main purpose for performing this study and should be focused on one question), outcome measures and method by which outcomes will be determined or state the hypothesis to be tested.

**Secondary Objective/Aim/Goal/Hypothesis**

Include secondary objectives (as many as relevant). These objectives may be dependent or independent of the primary objective.

**ENVIRONMENT HEALTH SAFETY OFFICE - EHS OFFICE**

**Does your study involve animals?**

If yes,

* Genus: [e.g., Mus]
* Species: [e.g., musculus]
* Strain, subspecies, or breed: [e.g., C57BL/6]
* Common name: [e.g., Black6]
* Approximate age, weight, or size:
* Sex:
* Bacteriological status: [e.g., germfree (axenic), defined flora (gnotobiotic), specific pathogen free (SPF), conventional]
* Viral status: [e.g., simian immunodeficiency virus, simian retrovirus]
* Source(s): [e.g., name of vendor or breeder, or bred in-house]
* Primary housing location(s): [Facility manager must certify in Section S that facility has the resource capability to support the study. If animals will be housed in lab or anywhere else outside central facility for more than 12 hours, provide building and room number.]
* Location(s) where manipulation will be conducted:
* Number of animals to be used per year:
* Total number of animals to be used:
* Transportation of animals must conform to all institutional guidelines/policies and federal regulations. If animals will be transported on public roads or out of state, describe methods you will use to comply with USDA regulations. If animals will be transported between facilities, describe the methods and containers that will be used. If animals will be transported within a facility, include the route and elevator(s) that will be used.
* Explain your rationale for animal use. [The rationale should include reasons why it is necessary to use animal models.]
* Justify the appropriateness of the species selected. [The species selected should be the lowest possible on the phylogenetic scale.]
* Justify the number of animals to be used. [The number of animals should be the minimum number required to obtain statistically valid results. Include justification for group size through a power analysis when possible.]

**Is your study related to drugs, biological products, medical devices, food supply, cosmetics, and products that emit radiation?**

If yes,

* Describe the type of variables will be collected (chemical, biological, radiation).
* Specify how and from where it will be obtained.
* Specify the need of the Laboratory Biosafety Levels 1, 2, 3 & 4.
* Describe where and how the materials will be stored.
* Specify who will have access to the stored materials and how will such access be secured and controlled.
* Describe if the materials be sent anywhere outside of the AdventHealth University and identify all locations.
* Describe the plans for disposition of data or specimens that are identifiable in any way (directly or via indirect codes) once the study has ended.
* Specify who will have access to this information and measures to assure confidentiality is maintained.

**METHODS INFORMATION**

**Study population, inclusion and/or exclusion criteria, sample size and method to determine the sample size.**

Identify the variables that will be collected. Describe how data will be identified, who is involved with data collection, analysis, storage, and destruction.

**Study Design/Methods/** **Instrumentation/Procedure:**

Include the description of study type (randomized double-blinded, placebo-controlled, open/off label, parallel or crossover design), number of study arms and other study details.

Describe if the study is quantitative (e.g. experimental, quasi-experimental, correlational, descriptive), qualitative (grounded theory, ethnographic, narrative research, or descriptive), or mixed combined (mixed method, action research).

Type of study and design should be decided based on primary and secondary objectives and availability of resources.

Describes the investigational component of the research. This includes drugs, devices, biologics, clinical intervention or other specific intervention, activities.

Describe the instrumentation for data collection and whether they are scientifically validated (i.e., include citation), how the study will be conducted, type of data (i.e., including organic material), where and how the data will be collected, stored (i.e., retention practice), and how organic material will be analyzed.

Explain the experimental design and specify all animal procedures. All procedures to be employed in the study must be described. This description should allow the IACUC to understand the experimental course of an animal from its entry into the experiment to the endpoint of the study. A flowchart may be an effective presentation of the planned procedure.

Include the following specific information, if applicable:

* Animal identification methods [e.g., ear tags, tattoos, collar, cage card, implant, etc.].
* Methods of restraint [e.g., restraint chairs, collars, vests, harnesses, slings, etc.]. Describe how animals are restrained for routine procedures like blood withdrawals. Prolonged restraint must be justified with appropriate oversight to ensure it is minimally distressing. Describe any sedation, acclimation or training to be used.
* Experimental injections or inoculations [substances, e.g., infectious agents, adjuvants, etc.; dose, sites, volume, route, and schedule].
* Blood withdrawals [volume, frequency, withdrawal site, and methodology].
* Radiation [dosage and schedule].
* Food or fluid restriction If food, or fluid, or both food and fluid, will be restricted, describe method for assessing the health and wellbeing of the animals. [Amount earned during testing and amount freely given must be recorded and assessed to assure proper nutrition.] If you are seeking a departure from the recommendations of the Guide, provide a scientific justification.
* Pharmaceutical-grade and Non-pharmaceutical-grade Compounds Identify any drugs, biologics, or reagents that will be administered to animals. If these agents are not human or veterinary pharmaceutical-grade substances, provide a scientific justification for their use and describe methods that will be used to ensure appropriate preparation and administration.
* Other procedures [e.g., survival studies, tail biopsies].
* Resultant effects, if any, that the animals are expected to experience [e.g., pain or distress, ascites production, etc.].
* Other potential stressors [e.g., noxious stimuli, environmental stress] and procedures to monitor and minimize distress. If a study is USDA Classification E, describe any non-pharmaceutical methods that will be used to minimize pain and distress.
* Experimental endpoint criteria [e.g., tumor size, percentage body weight gain or loss, inability to eat or drink, behavioral abnormalities, clinical symptomatology, or signs of toxicity] must be specified when the administration of tumor cells, biologics, infectious agents, radiation or toxic chemicals are expected to cause significant symptomatology or are potentially lethal. List the criteria that will be used to determine when euthanasia is to be performed. Death as an endpoint must be scientifically justified.
* Veterinary care Indicate the plan of action in case of animal illness [e.g., initiate treatment, call investigator prior to initiating treatment, euthanize].
* Surgical procedures [provide details of survival and non-survival surgical procedures.]

**If surgery is proposed, complete the following:**

* Identify and describe the surgical procedure(s) to be performed. Include preoperative procedures [e.g., fasting, analgesic loading], and monitoring and supportive care during surgery. Include the aseptic methods to be used.
* Identify the individual(s) that will perform surgery and their qualifications, training, and/or experience.
* Identify the location where surgery will be performed. [building(s) and room(s)]
* If survival surgery, describe postoperative care that will be provided and frequency of observation. Identify the responsible individual(s) and location(s) where care will be provided. [building(s) and room(s)] Include detection and management of postoperative complications during work hours, after hours, weekends and holidays.
* If non-survival surgery, describe how euthanasia will be provided and how death will be determined.
* Are paralytic agents used during surgery? If yes, please describe how ventilation will be maintained and how pain will be assessed.
* Has major or minor survival surgery been performed on any animal prior to being placed on this study? [Major survival surgery penetrates and exposes a body cavity or produces substantial impairment of physical or physiologic functions or involves extensive tissue dissection or transection (such as laparotomy, thoracotomy, craniotomy, joint replacement, or limb amputation)]. If yes, please explain.
* Will more than one survival surgery be performed on an animal while on this study? If yes, please justify.

**If anesthesia, analgesia, tranquilization, or other agents are involved, complete the following:**

For animals, specify the anesthetics, analgesics, sedatives, or tranquilizers that will be used. [A best practice is to provide an acceptable range of the specific items to allow flexibility in the use of professional judgment and avoid non-compliance due to work conducted off protocol as a result of overly restricted parameters.] Include the name of the agent(s), the dosage range, route(s) and schedule of administration. If information is provided in Section R.5., above, please cross-reference. Describe tracking and security of controlled drugs (Drug Enforcement Agency requirements).

**If a method of euthanasia or disposition of animals at end of study is involved, complete the following:**

Indicate the proposed method of euthanasia. If a chemical agent is used, specify the dosage range and route of administration. If the method of euthanasia is not consistent with the AVMA Guidelines for the Euthanasia of Animals, provide scientific justification as to why such method must be used. Indicate the method of carcass disposal.

**Study Site(s)/Location(s)/Sample size per location**

Institution, laboratory, hospital, or web-based site(s) of the data collection. You will need to upload the Study Site Contract(s) or Study Site Director Approval Letter(s) at the document page.

Include the information about number of sites. Keep in mind that you can have 1 site with multiple locations within that site. For example, AdventHealth University is a single site but can have multiple locations such as campuses, laboratories, etc.

Name the external site(s) outside of the AdventHealth University.

Include the sample group and size per site location, inclusion criteria, if applicable.

Include the total number of all sites.

Describe the communication plan with the study sites and include any recruitment methods and strategies (e.g., flyers, social media, cold calls). Attach copies of all recruitment materials in the attachment page.

**Timeline:**

Describe the timeline for completion of the project. Include when data collection is to be initiated, when the project implementation phase occurs, and when post implementation data will be collected. Shows the chronological order of events that you plan to do in your project. Use diagrams to illustrate the timeline.

**Data Analysis Plan:**

List study variables and describe the specific method(s)/tests for your study data analysis along with their underlying justification.

**Ethical Considerations/Privacy, Data Storage & Confidentiality:**

Describe any ethical considerations for the project and how they will be addressed. Limits to the generalizability of work, factors that may affect validity of measures etc. Potential risks for the researchers.

**Resources Available:**

Describe your process to ensure that all persons assisting with the research are adequately informed about the protocol, the research procedures, and their duties and functions.

Include your plan for ongoing discussion of issues throughout the duration of the study such as reportable new information, implementing amendments, study progress, etc.

Describe the qualifications (e.g., training, experience, oversight) of you and your staff as required to perform their role. When applicable describe their knowledge of the local study sites, culture, and society.

**Dissemination/Publication Plan:**

Please briefly describe how, when, and/or where you plan to disseminate the findings. If the request is for funds related to a prior research study, include a link to any publications or presentations of the study.

**DOCUMENTS PAGE**

**Upload the appropriate documents when submitting this proposal.**

* **Proposal** (this document)
* **Study Site Letter** (download template from https://my.ahu.edu/academics/research)

This letter acknowledges that the principal investigator has received approval to conduct the study at the identified study site. This letter needs to have the site logo, the Principal Investigator’s name, study title, facility’s name, facility director/responsible name, contact information, and signature. This letter is necessary:

* + When the study is collecting data outside of AHU, for example Cardiology Center of AH.
  + When the study collection or data analyses takes place in an AHU Center, Laboratory, or PI’s external department.
* **AHU Chair/Director Letter of Support** (download template from <https://my.ahu.edu/academics/research>)

This letter acknowledges that the department chair/director endorses that the principal investigator conducts the study as part of he/she work schedule and workload.

* **Questionnaire(s)/Survey(s)**

Any survey, questionnaire, or other instrumentation to gather data. It is expected that instrumentation is properly validated as much as possible.

* **Recruitment Materials**
* **Other Documents**