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# **Protocol Summary Form (PSF) For Animal Subject Research**

## *This form is to be used for all awardee applicants that envision the use of vertebrate animals for research or education purposes in CRDF Global sponsored research. Applicants are encouraged to submit this completed form as part of the proposal submission. CRDF Global reserves the right to request additional information from the applicant.*

## GENERAL PROJECT INFORMATION

|  |  |
| --- | --- |
| **Project Title** |  |
| **CRDF Global Proposal #** |  |
| **CRDF Global Program** |  |

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| --- | --- | --- | --- |
| [**Primary Investigator**](#PI) **(PI) and Institution Information** | | | |
| Name (Last, First, Middle) |  | | |
| Institution & Department |  | | |
| City, Country |  | | |
| E-Mail Address |  | | |
| Telephone |  | | |
| Are there any other institutes involved with the project? If yes, please provide institution information with this form. | | **YES** | **NO** |
| Will any individual involved with this study have contact with [animal subjects](#animalsubjects)? | | **YES** | **NO** |
| Will any individual involved with this study be involved with the collection of [biological samples](#biologicasamples)? | | **YES** | **NO** |
| Are the individuals involved with handling or collection of these [biological samples](#biologicasamples) trained on use and care of animals involved in research? If yes, please provide training certificates or other similar documentation with this form. | | **YES** | **NO** |

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| --- | --- | --- |
| **Study Description** | | |
| Provide project abstract (purpose, background, significance, research design and methods). | | |
|  | | |
| Describe the portion of the study involving [animal subjects](#animalsubjects). This should include any interactions with study subjects, collection of samples ([prospective](#prospective) or [retrospective](#retrospective)), and/or any procedures to be performed. | | |
|  | | |
| Describe why this study is necessary? Describe the reason [animal subjects](#animalsubjects) must be involved? Can this study be completed without using animals? | | |
|  | | |
| How will the proposed project benefit [animal subjects](#animalsubjects) and/or the community? | | |
|  | | |
| Are there any financial or personal [conflicts of interests](#conflictsofinterest) of the research team or affiliated institutions to disclose? | **YES** | **NO** |
| * If **YES**, describe: | | |
|  | | |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Type of Animal Subject Involvement** | | | | |
| Please classify the use of animal subjects in this activity. Check all that apply. | Research  Training  Observational | Sample Collection  Biological Testing  Experimentation | | |
| Will your research include: (check all that apply) | | | | |
| Use of **previously collected** animal biological samples ([retrospective study](#retrospective)).   * If **YES**, you must complete [Section II](#sectionII). | | | **YES** | **NO** |
| Handling or collection of **new** data and/or biological samples from animals ([prospective study](#prospective)).   * If **YES**, you must complete [Section III](#sectionIII). | | | **YES** | **NO** |
| Contact with animals for training or educational purposes.   * If **YES**, you must complete [Section IV](#sectionIV). | | | **YES** | **NO** |

## USE OF EXISTING BIOLOGICAL SAMPLES (RETROSPECTIVE STUDY)

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Obtaining Existing Samples** | | | | | |
| Provide the following information for existing samples. Duplicate for each different sample or animal type. | | | | | |
| Type of Animal | Sample type (i.e. blood, tissues, etc.) | | # of samples | | |
| *Ex. Sheep* | *Blood* | | *100* | | |
|  |  | |  | | |
|  |  | |  | | |
|  |  | |  | | |
| For what purpose were the samples originally collected? (i.e. for another study, as part of a routine veterinary clinic visit, for a repository, etc.) | | | | | |
|  | | | | | |
| Where were the samples obtained? (i.e. a previous study, a veterinary clinic, laboratory, etc.). State name of source. | | | | | |
|  | | | | | |
| Who has authority/ownership over samples? How did you obtain permission to use the samples? Describe the approval process. | | | | | |
|  | | | | | |
| Were the samples originally collected under a project approved by a [research ethics committee](#researchethics) (i.e. [IACUC](#iacuc))? | | | | **YES** | **NO** |
| If **YES:**   * List name of review committee entity (i.e. institute, government) and provide copies of ethics committee approval. | |  | | | |

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## COLLECTING NEW DATA AND/OR BIOLOGICAL SAMPLES (PROSPECTIVE STUDY)

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Type of Animal Subject Involvement** | | | | | |
| Provide the following information for collection of new samples. Duplicate for each different sample or animal type. | | | | | |
| Type of Animal | Sample Type | Body Site of Sample Collection | Method of collection (nasal / throat swab, [venipuncture](#venipuncture), surgery) | Sample amount taken (ml, tsp, grams) | # of times collected from each animal |
| *Ex. Sheep* | *Saliva* | *Mouth* | *Throat Swab* |  | *1* |
|  |  |  |  |  |  |
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|  |  |  |  |  |  |
| Provide details for any sample collection procedures that may not be clear from this table. | | | | | |
|  | | | | | |
| Describe why this animal species must be used in your research. | | | | | |
|  | | | | | |
| How did you decide the number of animals that will be used in this study? | | | | | |
|  | | | | | |
| Where will contact with animals take place? (check all that apply) | | | | | |
| In a laboratory setting (you must complete [Section III.A](#sectionIIIA)) | | | | | |
| In a veterinary clinic or hospital setting (you must complete [Section III.A](#sectionIIIA)) | | | | | |
| In the field: livestock from a farm, slaughterhouse, private home or other monitored setting (you must complete [Section III.B](#sectionIIIB)) | | | | | |
| In the field: wild animals (you must complete [Section III.B](#sectionIIIB)) | | | | | |
| Provide name and location of all above indicated performance sites (Add lines if needed): | | | | | |
| 1.  2. | | | | | |
| Please check all that apply to the collection of the biological samples: | | | | | |
| Samples are collected from live animals | | | | | |
| Anesthetic or other chemical substance is administered to live animals | | | | | |
| Surgery performed on live animals | | | | | |
| Implants or other devices administered in live animals | | | | | |
| Samples are collected [postmortem](#postmortem) | | | | | |
| Animal [euthanized](#euthanasia) as a result of sample collection | | | | | |
| Animal euthanized for research or teaching purposes | | | | | |

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| **Potential Pain and Distress to Live Animals** |
| Indicate the [level of potential pain](#pain), distress, or discomfort of an animal undergoing a procedure (including sample collection and trapping) or under observation in this study. |
|  |
| Describe the clinical signs or abnormalities that are expected or possible. |
|  |
| Describe how pain and distress will be monitored, including frequency and duration of checking for health or behavioral adverse effects. |
|  |
| Describe how pain, distress, and discomfort will be minimized (i.e. handling approaches or use of anesthesia, analgesia, tranquilization, other therapies, or euthanasia). |
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| **III.A. Use of Live Animals in a Laboratory, Veterinary or Clinic Setting** | | | |
| Where and how were the animals obtained? (i.e. collected in the field, purchased commercially, etc.) | | | |
|  | | | |
| Who is responsible for the care of the animals? Please include the individual/s profession, affiliation and experience. | | | |
| 1.  2. | | | |
| Who is responsible for the collection of samples? Please include the individual/s profession, affiliation and experience. | | | |
| 1.  2. | | | |
| Do you have, or plan to obtain, a [research ethics committee](#researchethics) approval for this study (i.e. [IACUC](#iacuc))? | | | |
| Planning to apply\* | Ethics review entity: |  | |
| Application submitted,  pending approval\* | Ethics review entity: | Application Date: |  |
| Approval received\* | Ethics review entity: | Approval Date: |  |
| Not planning to apply. |  | | |
| Other: \_\_\_\_\_\_\_\_\_\_\_\_ | | | |

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| **III.B. Use of Animals in Field setting** | | | | | |
| Who is responsible for the collection of samples? Please include the individual/s profession, affiliation and experience. | | | | | |
| 1.  2. | | | | | |
| Describe how the animals were identified for this study. | | | | | |
|  | | | | | |
| For livestock and other domesticated animals, will permission be obtained from the owner? | | | | **YES** | **NO** |
| If **YES**, describe you will explain the study, sample collection and how permission will be obtained (i.e. written or oral). | | | | | |
|  | | | | | |
| If **NO**, describe why owner permission is not required for the sample collection. | | | | | |
|  | | | | | |
| For wild animals, describe how the animals will be captured and released. | | | | | |
|  | | | | | |
| Do you have, or plan to obtain, a [research ethics committee](#researchethics) approval for this study (i.e. [IACUC](#iacuc))? | | | | | |
| Planning to apply\* | Ethics review entity: |  | | | |
| Application submitted,  pending approval\* | Ethics review entity: | Application Date: |  | | |
| Approval received\* | Ethics review entity: | Approval Date: |  | | |
| Not planning to apply. |  | | | | |
| Other: \_\_\_\_\_\_\_\_\_\_\_\_ | | | | | |

## USE OF ANIMAL SUBJECTS FOR TRAINING OR EDUCATIONAL PURPOSES

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| --- | --- | --- | --- |
| **Type of Animal Subject Involvement** | | | |
| Where and how were the animals obtained? (i.e. collected in the field, purchased commercially, etc.) | | | |
|  | | | |
| Who is responsible for the care of the animals? Please include the individual/s profession, affiliation and experience. | | | |
| 1.  2. | | | |
| Who is responsible for the handling of the animals? Please include the individual/s profession, affiliation and experience. | | | |
| 1.  2. | | | |
| Describe how the animals will be used in the planned activity. | | | |
|  | | | |
| Describe the procedure for handling the animals once the activity is finished. | | | |
|  | | | |
| Do you have, or plan to obtain, a [research ethics committee](#researchethics) approval for this study (i.e. [IACUC](#iacuc))? | | | |
| Planning to apply\* | Ethics review entity: |  | |
| Application submitted,  pending approval\* | Ethics review entity: | Application Date: |  |
| Approval received\* | Ethics review entity: | Approval Date: |  |
| Not planning to apply. |  | | |
| Other: \_\_\_\_\_\_\_\_\_\_\_\_ | | | |

## CERTIFICATIONS

I certify that the information above is true and accurate to the best of my knowledge. I understand that CRDF Global grant program funds may not be used to support animal subjects research beyond that described in this form and that any misrepresentation of research activities may result in forfeiture of the CRDF Global grant and inability to participate in any future grant programs.

|  |  |  |
| --- | --- | --- |
| Primary Investigator Signature |  | Date |
|  |
| Print Name & Title |

# Appendix B: GLOSSARY

**Animal Subjects:** A live or dead vertebrate animal used or intended for use in research, research training, teaching, experimentation or biological testing.

**Biological Samples:** A biological specimen, including, for example, blood, tissue, urine, etc.

**Conflicts of Interest:** A conflict of interest is a situation in which financial or other personal considerations have the potential to compromise or bias professional judgement and objectivity. An example of a potential conflict of interest includes investigators or institutions receiving compensation (i.e. receipt of equipment, honoraria, consulting fees, or proprietary interest in the product in the form of patents, trademarks, or licensing agreements) that may be affected by the outcome of the study.

**Euthanasia:** The humane destruction of an animal accomplished by a method that produces rapid unconsciousness and subsequent death without evidence of pain or distress; or a method that utilizes anesthesia produced by an agent that causes painless loss of consciousness and subsequent death.

**IACUC:** Institutional Animal Care and Use Committee. An organizational committee qualified through the experience and expertise of its members to assess a research facility’s animal program, facilities and procedures. Organizations may refer to an IACUC by a variety of other names, including Institutional Ethics Committee or Institutional Review Board.

**Painful procedure**: any procedure that would reasonably be expected to cause more than slight or momentary pain or distress in a human being, that is, pain in excess of that caused by injections or other minor procedures.

**Postmortem:** done, occurring, or collected after death.

**Primary Investigator (PI):** A PI is the primary individual responsible for the preparation, conduct, and administration of a research grant, training or public service project, contract, or other sponsored project in compliance with applicable laws, regulations, and institutional policy governing the conduct of sponsored research.

**Prospective Study:** A prospective study watches for outcomes, such as the development of a disease, during the study period and relates this to other factors such as suspected risk or protection factor(s). The study usually involves observing a cohort of subjects over an extended period of time.

**Research Ethics Committee**: A research ethics committee is formally designated by a research institution or a local governing body to ensure the protection of the rights, safety, and well-being of human subjects involved in a study and to provide public assurance of that protection by reviewing and approving/providing favorable opinion on the study protocol. Ethics committees exist under a variety of titles, including Research Ethics Committee, Institutional Review Board (IRB), Independent Ethics Committee, Ethics Review Board, Health Research Ethics Committee, etc.

**Retrospective Study:** A retrospective study looks backwards and examines exposures to suspected risk or protection factors resulting in an outcome of interest that has already occurred at the time the study is initiated.

**Venipuncture:** the puncture of a vein as part of a medical procedure, typically to withdraw a blood sample or for an intravenous injection.