



STANDARD OPERATING PROCEDURES

Section: A <i>General</i>	SOP Number: A.10.0
Subject: Research at Sabana Seca Field Station (SSFS)	Purpose: To outline requirements to submit a protocol to perform research at Sabana Seca
Written by: Marilyn Arce, DVM, DACLAM	Responsibility: All researchers
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RESEARCH PROTOCOL AT SABANA SECA FIELD STATION

Sabana Seca Field Station (SSFS) is the administrative headquarters and base of operations of the Caribbean Primate Research Center (CPRC) of the University of Puerto Rico-Medical Science Campus (UPR). The facility is mainly supported by the National Institute of Health (NIH)-Office of Research Infrastructure Programs (ORIP) and the UPR. As such, research activities performed at CPRC must abide to all federal state regulations regarding the use of laboratory animals.

I. PURPOSE

- A. To outline the requirements for performing a research project at the Sabana Seca Field Station Caribbean Primate Research Center (SSFS)
- B. To describe the steps that an investigator must follow in order to conduct a research protocol at SSFS
- C. To define the guidelines to be followed by all people interested in performing research at SSFS that involves the use of rhesus macaques as defined by the regulations
- D. To define Budgeting, invoicing, and any bench fee necessary to be established between the investigator and SSFS

II. RESPONSIBILITIES



STANDARD OPERATING PROCEDURES

- A. The principal investigator (PI) is responsible of providing the required information to the Director, Institutional Animal Care and Use Committee (IACUC), and the Institutional Biosafety Committee (IBC)
- B. The CPRC Director is responsible of pre-reviewing the Letter of Intent and send the research proposal to the CPRC Research Advisory Committee (RAC) for review, a seven-members internal and external committee that evaluates all research proposals submitted to CPRC.
- C. The RAC is responsible of reviewing the proposal, budget, and documents required
- D. The Attending Veterinarian or Associate Veterinarians with delegated responsibilities are responsible of reviewing the protocol before it is submitted to the IACUC for veterinary consult and committee review
- E. **Principal Investigators (PIs) should follow four steps:**
 - 1. Submit a Letter of Intent addressed to the CPRC Director. If a student is submitting the proposal, his/her supervisor (mentor) will be considered the PI, and the letter of intent should be signed by him/her
 - 2. Submit a research proposal to the CPRC Director for RAC review (RAC, SOP 8.0)
 - 3. Submit a request form for evaluation to IBC if the research involves the use of (a) infectious agents or hazardous chemicals, (b) animal blood, body fluids, cells or tissue, (c) recombinant or synthetic nucleic acid molecules
 - 4. Submit the research proposal to IACUC following RAC's approval, and send copy to the Attending Veterinarian and the Director of the CPRC

III. SUBMISSION GUIDELINES:

A. Letter of Intent:

- 1. Submit a letter of intent to the CPRC Director outlining the project, **PRIOR** to submitting a research proposal. If the project seems feasible and does not present a conflict of interest with on-going pursuits of investigators, the CPRC will provide details on the next step to follow, which include the review of the proposal by RAC and the forthcoming dates of IBC and IACUC meetings for the proposal submittal and requirements. When conflict or overlap of objectives with on-going investigators exist, the Director will inform the investigator submitting the new proposal about potential overlap without breaking rules of



STANDARD OPERATING PROCEDURES

confidentiality¹, and it is up to the researcher to decide whether or not to carry out the research.

B. Submit Proposal for RAC review:

1. Submit a research proposal to the CPRC Director, following his/her request. The proposal is expected to be submitted at least 90 days in advance of the proposed starting date.
2. A presentation of the proposal or meeting (phone or present) might be scheduled for the discussion of the project.
3. Proposals are evaluated for feasibility, budget and financial support, services available at SSFS and infrastructure. Proposals will be evaluated for scientific merit only if they will not undergo peer-review process (e.g., pilot projects)
4. Draft proposals are acceptable for RAC's review providing they do not differ significantly from the final version
5. If funding is sought, the proposal must be approved by the CPRC before it is submitted to a funding agency
6. After submission to a funding agency, the final version of the proposal must be sent to the CPRC's Director

REQUIREMENTS FOR PROPOSALS

The following items are essential for any proposal reviewed by RAC:

- Background and significance
- Hypotheses or purpose of project
- Materials and methods
- Budget (including CPRC bench fees: see below Bench Fee and Invoicing)
- Acknowledgment of CPRC's funding agency
- Data Sharing Plan after publication (see below Data Sharing Policy)
- The materials and methods of a proposal should indicate the species, sex, ages and number of animals to be studied. It must clearly describe the procedures to be performed, e.g. intramuscular injections, venipuncture; list of measurements to be obtained, etc. It must also include medicaments required for anesthesia, including dosage. All submitted proposals must contain a budget that includes CPRC fees before receiving final CPRC approval.

¹ CPRC should not disclose previous or on-going research projects, so duplication of field experiments may take place in the facilities. The Directorship will try to avoid this type of situation and will inform the PIs about possible duplication of experiments with other investigators.



STANDARD OPERATING PROCEDURES

C. Submit proposal to IACUC and IBC following RAC's approval

1. **IACUC PROTOCOL:** All researchers whose projects involve the study of nonhuman primates at the CPRC that involves **live** animals (including auditory, digital recordings, behavioral observations), **dead** animals, **tissue** sampling (organs, blood, feces, urine, other fluid samples) **must** submit their full proposals for independent evaluation by IACUC at UPR, and their home institution. The appropriate forms for the UPR-MS-C-IACUC are available at:
<http://committees.rcm.upr.edu/iacuc.html>

a. Submit proposal to:

- 1) **Institutional Animal Care and Use Committee (IACUC)**

Att: Elizabeth Rivera, DVM

University of Puerto Rico, Medical Sciences Campus
PO Box 365067, San Juan, Puerto Rico 00936-5067
Tel: (787) 282-0031 or (787) 758-2525 x 1836

- b. Send copy with **signed** signature page to the CPRC Director via email. The proposal must be reviewed by the attending veterinarian and he/she must sign the IACUC form before submission.
 - c. The **Institutional Animal Care and Use Committee (IACUC)** of the Medical Science Campus is responsible for the review of all animal care, research, breeding and educational/training protocols involving the use of monkeys at the CPRC. The IACUC then passes judgment on the proposal with special emphasis on whether or not the project meets USPHS policy on the humane care and use of animals and the USDA regulations established under The Animal Welfare Act, as amended. The IACUC may vote to approve, disapprove, defer a decision pending further information or an interview with an investigator, or approve the project conditionally if the investigator agrees to make the suggested changes in the protocol. If the committee feels that more information is needed or modifications of the proposal are necessary, the investigator will be contacted in writing and the project is re-reviewed the following meeting. Only after a proposal has been reviewed and approved, can it start.
2. **Biosafety Approval:** ALL research projects that involve the use of (a) infectious agents or hazardous chemicals, (b) animal blood, body fluids, cells or tissue, (c)



STANDARD OPERATING PROCEDURES

recombinant or synthetic nucleic acid molecules MUST obtain **Biosafety Committee approval** from IBC prior to starting the IACUC protocol. See the following website for the FORMS, deadlines, meeting agenda and other information needed. Website: <http://committees.rcm.upr.edu/biosafety.html>

NOTE: *** ALL proposals or research projects regardless of funding agency are reviewed by RAC (SOP 8.0) and require approval by the CPRC, IACUC, and IBC before any research can be conducted.

IV. MOU, BUDGET AGREEMENT/ FEE CONTRACT, AND INVOICING

1. **Memorandum of Understanding:** If the institution is not from the UPR system it must have a Memorandum of Understanding (MOU) signed between both institutions prior to the start of the RAC and IACUC evaluation process. The formal MOU needs to be established among all parties and signed by both Institutional Officials. MOUs must address the responsibility for animal care and use, animal ownership, and oversight.
2. A “**Budget Agreement / Fee Contract**” should be signed. The agreement must include all direct and indirect cost of the project for budgeting information.
 - a. **Please see CPRC Charge Sheet for fees**
3. Invoicing:

This information will be submitted to our administrator and a monthly invoice will be prepared for the institution of the PI.

Acknowledgment of CPRC’s funding agency

All PIs should agree to acknowledge CPRC’s funding agencies in their publications. PI’s should include in their publications the following statement: “The Caribbean Primate Research Center-Sabana Seca Field Station population is currently supported by the University of Puerto Rico (UPR) and the Office of Research Infrastructure Programs (ORIP) of the National Institutes of Health (2P40OD012217). The content of this publication is solely the responsibility of the authors and does not necessarily represent the official views of the UPR or ORIP.”

Data Sharing Policy

As an NIH funded facility, the CPRC follows the NIH policy on sharing research data (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html>). All PIs applying for research at the CPRC should include a Data Sharing Plan section in their research proposals addressing data sharing following the acceptance for publication of



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STANDARD OPERATING PROCEDURES

the main findings from the final dataset.