



RESEARCH PROTOCOLS AT CAYO SANTIAGO

FACILITIES AT CAYO SANTIAGO

Cayo Santiago Field Station (CSFS) is an off-campus facility administered by the Caribbean Primate Research Center (CPRC) of the University of Puerto Rico-Medical Science Campus (UPR). The facility is supported by the Office of Research Infrastructure Programs (ORIP). As such, we must abide the following guidelines established by ORIP: For each publication that results from grant support provided by the Office of Research Infrastructure Programs (ORIP), a component of the National Institutes of Health (NIH), grantees must include an acknowledgment of support and a disclaimer stating the following: *"This project was supported by grant number 2 P40 OD012217 from the Office of Research Infrastructure Programs (ORIP) of the National Institutes of Health."*

RESPONSABILITIES

Principal Investigators (PIs) should follow four steps to apply for research:

1. Submit a letter of intent addressed to the Director of CPRC. 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 Director of the CPRC for Research Advisory Committee (RAC) review.
3. Submit the research proposal to the Institutional Biosafety Committee (IBC), if applicable.
4. Submit the research proposal to the Institutional Animal Care and Use Committee (IACUC) following RAC's approval, and send copy to the Associate Director of Cayo Santiago.

The Director of CPRC is responsible of pre-reviewing the letter of intent and send the research proposal to RAC.

The RAC is responsible of reviewing the proposal, budget, and documents required.

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

GUIDELINES FOR PIs:

1. **Letter of intent:** Submit a letter of intent to the Director of CPRC outlining project. If the project seems feasible and does not present a conflict of interest with on-going pursuits of investigators, the Associate Director of CSFS will provide details on the next step to follow, which include the review of the proposal by RAC and the forthcoming dates of IACUC meetings (<http://committees.rcm.upr.edu/iacuc.html>) for the proposal submittal and requirements. When



conflict or overlap of objectives with on-going investigators exist, the Associate Director will inform the investigator submitting the new proposal about potential overlap without breaking rules of confidentiality¹, and it is up to the researcher to decide whether or not to carry out the research. However, if the protocol involves animal sacrifice, the Directorship should decline the petition.

2. Submit the proposal for RAC review: All scientists who plan to conduct research on CSFS are **REQUIRED** to submit proposals for their projects, (including pilot studies) a minimum of 90 days in advance of the proposed starting date. Proposals are evaluated for feasibility, budget and financial support, services available at CSFS and infrastructure. Proposals will be evaluated for scientific merit only if they will not undergo peer-review process (e.g., pilot projects). Draft proposals are acceptable for RAC's review providing they do not differ significantly from the final version. If funding is sought, the proposal must be approved by the CPRC before it is submitted to a funding agency. After submission to a funding agency, the final version of the proposal must be sent to the CPRC's Director.

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

1. Background and significance
2. Hypotheses or purpose of project
3. Materials and methods
4. Budget (including CPRC bench fees: see below Bench Fee Contract)
5. Acknowledgment of CPRC's funding agency
6. Data Sharing Plan after publication (see below Data Sharing Policy)
7. Copy of Application forms for the IACUC at UPR for all live animal studies (including behavioral studies).

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. A CPRC bench (use) fee, a handling or per sample fee and/or per diem for all monkeys in the study is charged for all projects.

3. Submit the proposal to the Institutional Biosafety Committee (IBC)

All researchers whose projects involve infectious agents, hazardous chemicals, human or animal body fluids, cell lines, or tissues **must** submit their full proposals for independent evaluation by IBC at UPR. The appropriate forms for the UPR-RCM-IBC are available at:

<http://committees.rcm.upr.edu/biosafety.html>

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.



4. Submit the proposal to IACUC following RAC's approval

All researchers whose projects involve the study of **live** animals (including auditory and digital recordings) **must** submit their full proposals for independent evaluation by IACUC at UPR, and their home institution. The appropriate forms for the UPR-RCM-IACUC are available at: <http://committees.rcm.upr.edu/iacuc.html>

Submit proposal to: Institutional Animal Care and Use Committee

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

Send copy with **signed** signature page to the Associate Director of Cayo Santiago via email. This page must be signed by the facility Manager and Veterinarian before reaching the committee.

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.

AGREEMENTS AND BENCH FEE CONTRACT

1. A Memorandum of Understanding (MOU) should be signed between institutions if the institution is not from the UPR system. The formal MOU needs to be established among all parties and signed by both Institutional Officials.

2. A Bench Fee Contract should be signed. The agreement must include all direct and indirect costs of the project for budgeting information.

Bench Fee Contract

A bench fee contract should be signed. However, if the data requested is not included in the bench fee contract, a formal written Memorandum of Understanding (MOU) needs to be established among all parties and signed by both Institutional Officials. The bench fee for use of the Cayo Santiago and Punta Santiago facilities is \$1,000 a month or \$33.33 per day prorated with an additional trapping fee of \$35 per monkey and \$45 for mother-infant pair. The cost of trapping an animal includes the first administration of ketamine and the initial services provided by the staff.



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The regular \$35 fee will be charged for any animal that is re-trapped during the same trapping season. Principal investigators (PIs) will be individually charged \$20 per animal for animals that are shared amongst investigators or for collecting samples from animals that are trapped for the needs of the Primate Center, such as yearlings. If the animal needs to be sedated more than once and processed during the following day, an additional processing fee of \$15 will be charged for sedative and veterinary assistance.

PIs must inform the amount of time they will be conducting research on Cayo Santiago or using the Punta Santiago office facilities to the Associate Director and Administrative Secretary of Cayo Santiago. This information will be submitted to our Sabana Seca headquarters and a monthly invoice will be prepared for the institution of the PI. Due to University regulations, bench fees and payments cannot be reimbursed to the investigators, but could be credited to the PI account. Requests for credit should be made in writing to the Associate Director 6 months prior departure from the island. If any active protocol participants will be absent from the CPRC facilities during the time previously specified as the data collection period, evidence of travel (e.g. airline tickets) must be presented to the Associate Director of Cayo Santiago in order to place a hold on daily fees.

Any investigator wishing an exception to the above policy must submit a written petition to the CPRC Director (cprc.rcm@upr.edu).

The \$1,000/month Bench Fee includes the following:

- Boat trips during scheduled hours for three people per protocol per month. An additional fee of \$12 per day will be charged for each additional person working at Cayo Santiago at any given time
- Access to conduct observations and non-invasive biosampling of IACUC approved number of subjects.
- Copy of monthly census.
- Access to monthly generated computerized demographic Cayo Santiago database. This information should be petitioned through Cayo Santiago Colony Manager and will be given only for accomplishing the objectives proposed.
- Use of office space, computers, WIFI, photocopy machines, bathrooms, water, refrigerators, temporary Revco storage, shop storage, masks, gloves, safety glasses, gauzes, paper towels, and disinfectant for the tables.
- Administrative support or assistance in coordinating housing or shipment and arrival of non-bio-hazardous materials.
- Bench space for those requiring laboratory analyses.
- Biohazard disposal.
- Herpes B Post-exposure sampling and transportation (only if needed) to clinic for treatment



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The \$1000/month Bench Fee **does not include** the following:

- Post exposure prophylaxis (i.e. to *Cercopithecine Herpesvirus 1*—acyclovir: generics cost on the upwards of \$500).
- Trapping and handling fees
- Laboratory supplies (test tubes, test tube racks, centrifuges, scales, ethanol, alcohol, etc.)
- Calls and Faxes outside of Punta Santiago, Puerto Rico. (All calls outside of area should be charged to a calling card or credit card)
- Transportation (final quote upon request):

Punta Santiago – University of Puerto Rico Medical Sciences Campus **RT \$75**

Punta Santiago – SJU Airport **RT \$75**

Punta Santiago – Sabana Seca **RT \$75**

Punta Santiago – PRAXAIR, Gurabo (dry ice) **RT \$35**

- Shipments of supplies and materials (e.g. FedEx, UPS).
- Housing

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 Cayo Santiago 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 (grant number 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 the main findings from the final dataset.

ACCESS AND MEDICAL CLEARANCE

This process must be followed if you have received entrance approval to the island of Cayo Santiago by the CPRC Cayo Santiago Associate Director.

All researchers must submit a completed Medical History Form and the following documents to the Occupational Health Office (OHO) at the UPR Medical Sciences Campus:

- a. Completed medical history form
- b. Results of fecal exam for ova & parasites
- c. Results of fecal culture for Salmonella and Shigella



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- d. Results for measles titers IgG (Rubeola) (Only for individuals born after 1957/those born before 1957 do not have to perform the test, but must include a copy of a valid identification that specifies date of birth (e.g. driver's license)
- e. Results of negative tuberculin (Tb) skin test obtained within six months, or if skin test results positive a chest x-ray must be performed within one year prior to entry on the island
- f. Evidence of Diphtheria Tetanus vaccination (DT vaccine), which is required due to the high prevalence of Tetanus disease on Cayo Santiago

Only tuberculin test must be repeated if the extent of your stay is beyond six months of the initial skin test or 1 year when submitting an X-ray. Also in case of suffering a gastrointestinal episode during your stay at Cayo Santiago, you must follow the instructions specified in Section C of this protocol.

All other documents submitted to the OHO are to be presented only at initial submission.

Submit all documentation at least 30 days prior to date of arrival. Please note that if you do not comply with this deadline you will not be allowed to enter the field site. Submit to:

Juanita Rivera

Occupational Health Nurse

UPR Medical Sciences Campus

Phone: (787) 758-2525 ext. 2910 / 2913 Fax: (787) 758-7441 juanita.rivera1@upr.edu

Once the package has been submitted you shall confirm receipt via telephone with the Occupational Health Nurse at (787) 758-2525 ext. 12913. Also send an email to the Occupational Health Coordinator at Cayo Santiago Ms. Nahiri Rivera (nahiri.rivera@upr.edu) for assistance on follow up with the OHO. Ms. Nahiri Rivera will follow up with the OHO nurse for any documents pending from the initial submission; and inform accordingly to the researcher.

Once the package is evaluated by the OHO doctor, the Occupational Health Nurse will send a signed medical clearance via email and/or fax to the Occupational Health Coordinator at Cayo Santiago. The OHO doctor is only available on Tuesdays and Fridays to evaluate and generate medical clearances.

The medical clearance will include the expiration date of the Tb test for each individual. The Occupational Health Coordinator at Cayo Santiago must monitor all TB test expiration dates, and notify researchers when they must repeat the test and submit the most updated version to the Occupational Health Nurse.

The Occupational Health Coordinator at Cayo Santiago will inform the researcher once medical clearance to enter the island of Cayo Santiago has been attained.



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If the researcher wishes to return to the facility after one year has passed from the initial medical clearance, the researcher must contact the Occupational Health Coordinator at Cayo Santiago who will coordinate send a Follow Up Medical History Questionnaire which contains information about any current health conditions that may have occurred after the initial medical clearance was obtained.