



**INTER AMERICAN UNIVERSITY OF PUERTO RICO
INSTITUTIONAL REVIEW BOARD**

**APPLICATION TO INVOLVE
HUMAN SUBJECTS IN RESEARCH
(Form ORE-IRB-1)**

TITLE: Estudio sobre la Intrusión de Ruido Ambiental en Dos Reservas Naturales de la Costa de P.R.

PRINCIPAL INVESTIGATOR'S NAME, TELEPHONE AND POSTAL ADDRESS:

Prof. Ernesto Torres

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DEPARTMENT CS NATURALES

PROGRAM CAMPUS METRO

NAME, TITLE, TELEPHONE AND ADDRESS OF ALTERNATE CONTACT: (FACULTY RESEARCH ADVISOR OR DEPARTMENT CHAIRPERSON)

Prof. Dagmar Pelegrina(787)250-1912 x-2323/2325

Dr. Izander Rosado Lozada (787)250-1912 x-2142

Date Submitted: 21 de noviembre de 2008

Project Time Period:

Start Date: 01/11/08

Ending Date: 30/06/09

Other Participating Institutions Including Subcontractors: Yes ___ No

Participating Institutions requiring other IRB review: Yes ___ No

Where Will the Research Be Conducted?: Reservas Naturales Laguna Tortuguero, Vega Baja y La Esperanza en Manatí

For IRB use Only:

Application Status: New ___ Addendum ___

IRB Number: _____

Date Received: _____

Type of Review: Full: ___ Expedited: ___ Exempt: ___

Information Requested for Clarification:

Actions:

Date: _____

Contact

Vice Presidency for Academic Affairs and Systemic Planning

IRB Administrator

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PROTECTING THE RIGHTS AND WELFARE OF HUMAN SUBJECTS IN RESEARCH AT INTER AMERICAN UNIVERSITY OF PUERTO RICO

The purpose of this application is to promote careful thought regarding the involvement and ethical treatment of human subjects in research, ensure compliance with federal, state, and corporate regulations, and elicit from the Principal Investigator, pertinent information which will facilitate a rapid and thorough review by the IAUPR Institutional Review Board (IRB).

“Notes” are provided as guidelines to help answer specific questions. Please answer each question or indicate that it is not applicable to the research being conducted. Call the IRB Administrator if you have questions.

SUMMARY GUIDELINES

IAUPR policy requires that all research involving human subjects* conducted by or under the direction of IAUPR personnel and students using any property or facility of IAUPR, regardless of location, must be submitted to the IRB for review and approval.

Written notice of IRB approval must be issued before the Principal Investigator (PI) may initiate research. **Only those documents (consent form, advertisement, questionnaires, etc.) that bear the IRB approval stamp may be used in the conduct of research.**

Any change made to the protocol, consent form, or supporting documentation must be approved by the IRB before they can be implemented, as well. A review may be requested by submitting an addendum application to the IRB.

The IRB cannot approve a protocol for a period longer than one year and cannot, under any circumstances, grant retroactive approval. Continuing review is, therefore, required on a yearly basis. The IRB will issue a notification when an Application for Continuation is due. However, the Principal Investigator is responsible for ensuring that applications are submitted and approved before work is initiated and/or continued.

- **Human Subjects** are defined by the federal regulations as “living individual(s) about whom an investigator conducting research obtains 1) data through intervention or interaction with the individual, or 2) identifiable private information”

**Checklist
Application for IRB Review**

Required Documentation for a New Application

Application to Involve Human Subjects in Research (IRB-1)

A CD containing documents in MS-WORD format, regarding the application: Consent and/or Assent Documents, IRB-1 Form, instruments that will be used or administered to research participants, etc.

Statement of Work or Research Proposal - Send any information that you feel may help the IRB review the project, for example: The Methodology in a thesis proposal.

This list indicating materials submitted.

Informed Consent Document (signed by PI)

_____ DEPR exclusion clause if applicable

_____ IAUPR Clause for protocols involving DEPR students, parents or DEPR personnel

_____ Waiver of Signed Consent if applicable

Assent Document for protocols involving minors

Authorization letters duly signed by authorized representatives

Copies of documents indicating other on-going IRB review Board processes and/ or approval letters.

Advertisement, flyers, solicitation or other relevant documents or information that will be provided to participants

Questionnaires/surveys if applicable

PLEASE DO NOT BIND AND/OR STAPLE THE RESEARCH PROTOCOL APPLICATION OR ANY DOCUMENTS INCLUDED WITH THE APPLICATION THAT WILL BE PROVIDED TO RESEARCH PARTICIPANTS (USE CLAMPS)

Investigator's Assurance

I certify that the information provided in this application is complete and correct. I understand that as Principal Investigator, I am responsible for the conduct and ethical performance of this project, the protection of the rights and welfare of human subjects, and strict adherence to any stipulations imposed by the IAUPR Institutional Review Board.

I agree to comply with all policies and to:

- accept responsibility for the scientific and ethical conduct of this research study;
- to obtain prior approval from the Institutional Review Board before amending or altering the research methodology or implementing changes in the approved consent form;
- to immediately report to the Institutional Review Board any serious adverse reaction and/or unanticipated effects on subjects which may occur as a result of this study;
- to obtain a legally effective Informed Consent form from human subjects or their legally responsible representative, and using only the currently approved, stamped, consent form.
- to complete, on request by the Institutional Review Board, the Continuation/Final Review Forms

Prof. Ernesto Torres _____ 21/11/08
Principal Investigator (Typed/printed) Signature Date

Department Affiliation Cs. Naturales _____ Campus Metropolitano _____

Department Chairperson's Assurance Statement

This is to certify that I have reviewed this research protocol and that I attest to the scientific merit of this study and the competency of the investigator(s) to conduct the project. *(If the principal investigator is also the chairperson of the department, the Dean should sign the Signature Assurance Sheet)

Prof. Dagmar Pelegrina _____ 21/11/08
Chairperson's Name (Typed/printed) Signature Date

Dr. Izander Rosado Lozada _____ 21/11/08
Chairperson's Name (Typed/printed) Signature Date

Department Affiliation Cs. Naturales _____ Campus Metropolitano _____

Student's Faculty Research Advisor Assurance Statement

This is to certify that I have reviewed this research protocol and that I attest to the scientific merit of this study and the competency of the investigator(s) to conduct the project. *(If the Principal Investigator is completing this project to meet the requirements of a Inter American University of Puerto Rico program, the student's faculty research advisor should sign the Signature Assurance Sheet)

Faculty Name (Typed/printed) Signature Date

Department Affiliation _____ Campus _____

I. SUMMARY

A. Will the research involve any of the following?

<input type="checkbox"/> Interviews	<input type="checkbox"/> Use of bodily materials from a living individual or fetus
<input type="checkbox"/> Use of private information	<input type="checkbox"/> Genetic research/analysis
<input type="checkbox"/> Use of private data/records	<input type="checkbox"/> Genetic notification
<input checked="" type="checkbox"/> Survey/questionnaire	<input type="checkbox"/> Data or tissues obtained specifically for this project
<input type="checkbox"/> Behavior observation	<input type="checkbox"/> Investigational drugs
<input type="checkbox"/> Deception	<input type="checkbox"/> Investigational devices or materials
<input type="checkbox"/> Waiver of consent	<input type="checkbox"/> Study of existing documents
<input type="checkbox"/> Controlled substance	<input type="checkbox"/> Minor change to previously approved research
<input type="checkbox"/> Study of diagnostic specimens	<input type="checkbox"/> Human in vitro fertilization
<input type="checkbox"/> Study of pathological specimens	<input type="checkbox"/> Micro-organisms or recombinant DNA
<input type="checkbox"/> Venipuncture (<450cc)	<input type="checkbox"/> PI or alternate as attending physician or care giver
<input type="checkbox"/> Radiation	<input type="checkbox"/> Environmental alternations (habitat/lighting, etc)
<input type="checkbox"/> Personal identifying links to data	<input type="checkbox"/> Audio visual/tape recordings or photographs
<input type="checkbox"/> Clinical Studies	<input type="checkbox"/> Moderate exercise by volunteers
<input type="checkbox"/> HIV/Aids	<input type="checkbox"/> Individual observation or group behavior or characteristics
<input type="checkbox"/> Hepatitis/TB/STD	<input type="checkbox"/> Tools developed specifically for this study
<input type="checkbox"/> Culturally or socially Sensitive Issues	
<input type="checkbox"/> Potential development of commercial products from human biological materials	

B. Using non-technical lay language, please provide:

(1) A brief description of the scientific objectives of the research.

El proyecto propuesto se enfocará en los siguientes objetivos:

- Establecer un perfil general de la intrusión de ruido ambiental y su efecto en la biodiversidad animal inmediata.
- Evaluar el nivel de conocimiento de los visitantes sobre la generación de ruido ambiental en el entorno urbano y natural.
- Ampliar la obtención de datos y resultados que permitan el desarrollo de planes de manejo y protección adecuados, así como futuras investigaciones y actividades de educación a la comunidad.

El perfil general de la intrusión de ruido ambiental se establecerá mediante la recopilación de datos a través de una serie de muestreos sonométricos en ambas reservas naturales. De otra parte la información relacionada con el nivel de conocimiento sobre la generación de ruido ambiental, se obtendrá mediante la administración de un cuestionario validado y autorizado por la JCA.

(2) A brief, but specific description of the procedure(s) involving the human subjects. (If it will be pilot testing or trials, please specify how it will be conducted?). (USE ADDITIONAL PAGES IF NECESSARY).

El *Cuestionario de Opinión Sobre Ruido Ambiental* (preparado por la Junta de Calidad Ambiental), será administrado a por lo menos 60 personas que visiten el área recreativa de la Laguna Tortuguero, durante los meses en que sean efectuados los muestreos. Los cuestionarios se administraran al azar en diferentes días.

II. THE HUMAN SUBJECTS

- A. How many human subjects will be involved approximately?**
Number:60 **Age Range:** 18 en adelante **Sex:** ambos (masculinos y femeninos)
- B. Period of involvement of human subjects? Date: From** febrero 2009 **to** marzo 2009
- C. Will the research involve any of the following subject population?**

<input type="checkbox"/> Children under 21 years old*	<input type="checkbox"/> Terminally ill*
<input type="checkbox"/> Elderly*	<input type="checkbox"/> Comatose
<input type="checkbox"/> Pregnant women*	<input type="checkbox"/> Cancer patients
<input type="checkbox"/> Fetuses*	<input type="checkbox"/> Cognitively or psychologically impaired*
<input type="checkbox"/> Prisoners or parolees*	<input type="checkbox"/> Non-English or Spanish speaking*
<input type="checkbox"/> IAUPR staff or families*	<input type="checkbox"/> Mental patients*
<input type="checkbox"/> Institutional residents*	<input type="checkbox"/> Human in vitro fertilization
<input type="checkbox"/> Genetically susceptible/impaired	<input type="checkbox"/> Unable to give informed consent
<input type="checkbox"/> Any population excluded	<input type="checkbox"/> Military personnel and/or immediate family
<input type="checkbox"/> Emergency patients*	<input checked="" type="checkbox"/> Culturally/ethnically, or other diverse subjects
<input type="checkbox"/> Physically impaired*	
<input type="checkbox"/> Students	
<input type="checkbox"/> Other (persons working or studying with PI)	
* Vulnerable subjects	

* IUAPR students

D. Will any vulnerable subjects (*) be included? If so, please identify and justify their involvement.

N/A

E. Who are the human subjects? Provide details for population(s) checked. Describe by age, gender, special characteristics, traits, etc.

F. How, and by whom, will the human subjects will be identified and recruited?. Explain type of method(s) to be used in the identification contact and recruitment of subjects. Attach a copy of any planned advertisements/notices and letters to potential subjects. If the process is detailed in another document submitted to the Board. Please indicate document page number).

Note: Equitable inclusion of both men and women of all ages, and individuals from diverse racial/ethnic backgrounds is important to ensure that they receive an equal share of the benefits of research and that they do not bear a disproportionate share of its burdens. Participation should not be restricted without medical or scientific justification.

G. Explain how the relationship with the human subjects will be established?. (If the researcher, assistants or someone related to them has a personal or professional relationship to the subjects, explain in detail the procedures adopted to avoid coercion and/or maintaining confidentiality.) If a vulnerable population is included explain procedures adopted to avoid coercion.

Note: The identification and recruitment of subjects must be ethically and legally acceptable and free of coercion. Procedures used to recruit subjects should be designed to reach diverse populations. Vulnerable subjects, such as persons in nursing homes or institutions, should not be recruited merely for the sake of convenience.

III. RISKS AND BENEFITS

A. Risk Classification: What is the overall risk classification of the research:

- minimal**
- greater than minimal**
- significant**
- or unknown?**

Note: According to DHHS/FDA regulations, minimal risk means “The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests”. “When the risks associated with a new procedure or product are unknown, they cannot be classified as minimal”.

B. Potential Risks and Discomforts: What are the potential risks/discomforts associated with each intervention or research procedure? If data are available, estimate, a) the probability that a given harm may occur, b) its severity, and c) its potential reversibility. Include what physical, emotional or social risks that will be faced by the participants.

N/A

Note: A risk/discomfort is a potential harm associated with the research that a reasonable person would consider important in deciding whether to participate in the research. Risks can be generally categorized as physical, psychological, sociological, economic, and legal.

Note: In research involving more than minimal risk, capacity to consent should be determined by a psychiatrist, clinical psychologist, or other qualified professional not otherwise involved in the research. Individuals who lack the capacity to consent may participate in research only if a legally authorized representative gives consent on their behalf.

C. Minimizing Risks: What specific steps will be taken to prevent/minimize any potential risks or discomfort?

N/A

Note: All potential risks and discomfort must be minimized to the greatest extent possible by using procedures such as appropriate monitoring and withdrawal of the subject upon evidence of a specific adverse event or clinical sign(s). This section should reflect that all appropriate steps will be taken to protect subjects from harm.

D. Adverse Events: How and who will handle adverse events? Are facilities and equipment adequate to handle adverse events?

E. Potential Benefits:

1) What potential benefits, if any, may the subjects receive as a result of their participation in this research?

2) What potential benefits to society may be expected from this research?

Note: Societal benefits generally refer to the advancement of medical or scientific knowledge and/or possible future benefits.

F. Therapeutic Alternatives: What therapeutic alternatives are reasonably available in the non-research and/or research context that may be of benefit to the potential subjects?

N/A

Note: This section should include a reasonably detailed description of the therapeutic alternative that could be used to treat the patient should they elect not to participate in the protocol.

IV. FINANCIAL CONSIDERATIONS

A. Cost: Will there be a compensation given for participation? Which cost will be reimbursed for travel and other expenses, if any? Will they receive services or other benefits instead of cash? What conditions must be fulfilled to receive full or partial payment?

N/A

V. INFORMED CONSENT

Note: This section should clearly document that the investigator has an adequate plan in place to ensure existence of an acceptable level of comprehension before consent is documented. Willingness to sign the consent form is not an adequate demonstration of their understanding. Some investigators try to determine the level of prospective subjects comprehension by questioning them about the research. This approach is useful with children and adolescents, as well as with adults of uncertain capacity to consent.

A. Does the informed consent procedure incorporate the following basic elements:

- A simple and clear explanation of the purpose of the research and chronological description of the procedures the volunteer will be involved in, including an identification of those that are experimental.

- A description of the attendant discomforts and risks.
- A description of possible benefits.
- An explanation of compensation to be expected.
- A statement describing how privacy of data or personal information will be maintained.
- A disclosure of appropriate alternative procedures that might be advantageous for the subject.
- An offer to answer any inquiries concerning the procedures.
- An instruction that the subject is free to withdraw his or her consent and to discontinue participation on the project or activity at any time.
- Available sources of information and an explanation that the subject is free to ask questions at any time during the study.
- Adequate documentation of informed consent.
- Documentation of the method for informing subjects of the results of their participation in the research.
- Statement of Informed Consent for use of video or recording.

B. Process of Consent: Please provide a brief but detailed description of the informed consent procedure to be employed to protect human subjects from undue influence or coercion.

Note: Only those individuals authorized to solicit consent may sign the consent form confirming that the prospective subject was provided the necessary information and that any questions were answered. Consider: a) the environment and location where informed consent will be solicited; b) the timing of the process (e.g., in relation to hospital admission, work situation, stressful events); c) involvement of someone other than the investigators to help explain the research; and d) opportunity (ample time) for the prospective subjects/representatives to discuss participation in the research with family, friends, or their advisors before signing the consent form

VI. INVOLVEMENT OF OTHER INSTITUTIONS

1. Describe any arrangements or agreements with other institutions which will directly affect the involvement of human subjects in this research. If applicable, provide letters of cooperation and or authorization.

2. Will human subjects review be required by any other institutions?

Yes ___ Name of Institution: _____

No ___

3. Will research results be available to the institution in such a manner that participants can be easily identified? (Please elaborate).

VII. UNUSUAL ASPECTS OF THIS RESEARCH

Please note any unusual aspects of this research, which should be called to the attention of the Institutional Review Board for Human Subjects Research and may affect the rights of the Human Subjects.

N/A

VIII. DATA MANAGEMENT AND DISPOSAL

Please explain how data will be managed during the research process and how it will be stored or destroyed. If video or recordings were obtained, explain how it were obtained and the method of disposal.