1. Project Identification and Abstract

1.1. *Type of Submission:

- Research Protocol or Study on Human Subjects
- Grant/Contract Only
- Facilitated Review (NCI CIRB)
- USC/CHLA Collaborative Review
- Use of Humanitarian Use Device (Not Research)
- Ceded Review (Utilize approval by an outside IRB)

1.2. *Full Title of Research Protocol

Urban Sustainability through Sustainable Wastewater Initiatives in Tijuana, Mexico

1.3. *Short Title

Sustainable Wastewater Treatment in Tijuana

1.4. Abstract: Provide a simple explanation of the study and briefly address (in 1 to 2 sentences) each of the following points: rationale; intervention; objectives or purpose; study population or sample characteristics; study methodology; description of study arms (if appropriate); study endpoints or outcomes; follow-up; statistics and plans for analysis.

- The objective of this study is to evaluate sustainable wastewater initiatives in Tijuana, Mexico. Wastewater refers to liquid sewage, or effluent discharged from houses. Traditional wastewater treatment technology relies heavily on water for transportation and dilution of wastes. Tijuana is located in an arid region with scarce water resources. In an effort to reduce reliance on water-based treatment systems, several new treatment technologies have been incorporated into new plants. I will conduct interviews with key stakeholders in Tijuana’s wastewater community to facilitate the comparison of the contributions of a centralized treatment plant, Planta de Tratamiento de Aguas Residuales (PTAR) Arturo Herrera, and an alternative treatment plant, Ecoparque, to the city’s ecological sustainability and environmental health. Interview participants have unique insights into the planning, construction, and operation of the two plants. A content analysis of the interviews will support a sustainability indicator analysis and identify opportunities and challenges for adopting additional sustainable treatment technologies in other parts of the city.

1.5. *Select which IRB you are requesting review from:

USC-University Park Campus (UPC)

2. Study Personnel

2.1. Study Personnel and their roles:

<table>
<thead>
<tr>
<th>Last Name</th>
<th>First Name</th>
<th>Organization</th>
<th>Study Role</th>
<th>Certifications</th>
<th>Obtain Consent</th>
</tr>
</thead>
</table>
2.2. Is the Principal Investigator a student, resident, fellow, other trainee, or visiting scholar at USC/CHLA?  
  ☐ Yes ☐ No

Please Designate a Faculty Advisor in 2.1.

2.3. If there are any individual collaborators from other institutions, check here: ☐

2.5. Specify the group/organization who has reviewed this study for scientific merit:

4. Funding Information

4.1. * What existing, planned, or pending support will be used for this study? (check all that apply)  
  ☐ Cooperative Group (SWOG, COG, RTOG, etc.)
  ☐ CTSI
  ☐ Department of Defense (DOD) Funds
  ☑ Departmental/Institutional Funds
  ☑ Federal Grant/Contract
  ☐ Foundation Grant/Contract
  ☐ Industry
  ☐ Intramural/Internal Grant
  ☐ Residual Funds
  ☐ State or Local Grant/Contract
  ☐ Subcontract from another institution
  ☐ No Funding
  ☐ Other

4.2. If the funding source has undergone separate review by the IRB (i.e., cooperative group grants, umbrella grants, multi-project/program grants, center grants), try to select it from the list using the "Add" button. If the funding source is not displayed in the list, enter the information in question 4.4.

Grant #  Principal Investigator  Grant Title

There are no items to display

4.2.1. If the grants selected in question 4.2 fund multiple studies, please attach the specific pages of the grant that are relevant to THIS study.

name  Version  Modified

There are no items to display
5. Type of Study Review

5.1. Select the type of review that you are requesting for this study:

- Full Committee Review
- Expedited Review
- Exempt Review
- Coded Specimens/Data

5b. Type of Study Review - Application for Exempt Status

This screen is required if you are requesting a claim of exemption for this study (Question 5.1.) If this is the incorrect review type, please return to page 5 to make changes.

WARNING: A Claim of Exemption is not allowed for any research involving prisoners. In these cases, you must request Expedited Review.

5b. Choose the applicable exemption categories from the list below. (Note: these exemptions do not apply to research involving prisoners. For children, all exemption categories may apply except for (2) unless it is simply observation of public behavior and the investigator does not interact with the children.)

- (1) Research conducted in established or commonly accepted educational settings, involving normal educational practices...
- (2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior...
- (3) Research involving the use of educational tests, survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section...
- (4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens...
- (5) Research and demonstration projects which are conducted by or subject to the approval of Department or Agency heads, and which are designed to study, evaluate, or otherwise examine...
- (6) Taste and food quality evaluation and consumer acceptance studies...

5b.2. Do you intend to enroll or study minors in the research?

- Yes
- No

***** WARNING: This Study May Not Qualify For Exempt Category 2! *****

For Exempt Category 2 to apply, the study activities must be limited to observation of public behavior of minors (no participation) unless the study is at USC, has no funding, and is determined to qualify
6. Study Location(s)

6.1. Select the locations where this study will be conducted by the USC/CHLA investigator(s) (check all that apply):

- HSC - Health Sciences Associated Locations
- **UPC - University Park Associated Locations**
- CHLA

6.2. Are there other sites besides USC/CHLA involved in the research?

- Yes
- No

6.3. Is USC/CHLA the coordinating site or are there sites where USC/CHLA is conducting the study?

- Yes
- No

6b. UPC Location(s)

This screen is required if you indicated UPC - University Park Associated Locations (Question 6.1.)

6b.1. UPC Locations (check all that apply and provide detail where indicated):

- Campus location (includes ISI and ICT)
- **Off-campus location**

If campus location, please specify:

6b.2. If off-campus location, please specify:

- Offices of interview participants

9. Methods and Procedures - Selected Descriptors/Community Engaged Research

Note: The list of items below IS NOT an all-inclusive list of methods and procedures available to investigators. The list only includes items that will trigger additional questions specific to areas of research or are necessary for the review process.

9.1. This study will involve: (check all that apply)

- Prospective collection of data/specimens
- **Use of existing or retrospective data/specimens**

9.2. Study Procedures: (check all that apply)
9.4. Will data from this study be submitted to the NIH Genome-Wide Association Studies (GWAS) data repository?  
☐ Yes  ☐ No

9.5. Does your study involve community-engaged research (community-engaged research addresses community needs and involves the community in research plan, conduct of study, etc)?  
☐ Yes  ☐ No

11. Study Design and Methodology

11.1. Describe in detail the design and methodology of the study. If applicable, include information on stratification or randomization plans. Identify and distinguish between those procedures that are standard of care and those that are experimental. Include the frequency and duration of each activity and the total length of subject participation.

• In this qualitative study, I will use semi-structured interviews to collect data. Each interview will follow a predetermined schedule of questions with an open response design, but will be flexible to expand on informant responses. The majority of interviews will take place during the summer and fall semesters.
• Up to 16 semi-structured interviews with key government officials as well as staff members, volunteers, and funding sources for Ecoparque will establish the role these facilities play in bridging the gap between the brown and green agendas. Participants will be interviewed once. These interviews will last between 60 and 90 minutes.
• Interviews will be preceded by pilot interviews to test the interview schedule and uncover any problems that may arise during the interviews, including issues with question style, wording, or local factors that may impact the research process.
• Interviews will be conducted in the language preferred by the participant, either English or Spanish.

11.2. Provide a description of the study population.
19. Methods and Procedures - Interview/Focus Groups

This screen is required if you indicated the use of Interview or Focus Groups as a procedure (Question 9.2.)

19.1. Attach copies of any scripts and/or questions that will be used to guide the interviews/groups.

<table>
<thead>
<tr>
<th>Name</th>
<th>Version</th>
<th>Modified</th>
</tr>
</thead>
<tbody>
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</tr>
<tr>
<td>Herrera</td>
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</table>

22. Special Subject Populations

22.1. Indicate any vulnerable subject populations you intend or expect to enroll in the research:

- Normal Volunteers
- Employees or Students
- Adults not Competent to Consent (or likely to lose the capacity to consent during the study)
- Non-English Speaking Populations
- Minors (subjects under 18 years of age)
- Pregnant Women / Human Fetuses
- Neonates (infants under 30 days old)
- Prisoners/Detainees
- Wards
- None of the above

24. Subject Recruitment and Informed Consent

24.1. Recruitment Tools that will be used by the local site (check a box only if your site will control the use or distribution of the recruitment tool): (check ALL that apply)

- E-mail/Electronic Mailing List
- Brochure
- Flyers
- Letters
- Newspaper/Magazine Advertisements
- Radio/Television Announcements
- Subject or Participant Pool
- Telephone Scripts
- Verbal (Personal Solicitation)
- Website / Social Media Outlets
24.1.2. **Describe how you will be obtaining contact information:**

Emails, mailing addresses, and telephone numbers are obtained from Tijuana's public services commission (CESPT) website or the Ecoparque website.

24.2. **Attach copies of all recruitment tools that will be used at the local site.** *(Do not attach any advertising or recruitment materials that are provided by a sponsor that cannot be modified by the local site.)*

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<th>name</th>
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<tbody>
<tr>
<td>There are no items to display</td>
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</tr>
</tbody>
</table>

24.3. **Will you be obtaining informed consent, assent, parental permission, or be providing participants with information sheets?**

- [ ] Yes
- [ ] No

24.4. **Attach copies of the informed consent documents(s), information sheets, and any statements of new information/findings or consent addenda (as applicable) that will be used in this study. This set should also contain any assent or parental permission documents that will be used.**

<table>
<thead>
<tr>
<th>name</th>
<th>Version</th>
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24.5. **Personnel from section 2.1 obtaining consent/permission/assent:**

<table>
<thead>
<tr>
<th>Last Name</th>
<th>First Name</th>
<th>Organization</th>
<th>Study Role</th>
<th>Certifications</th>
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</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>SPATIAL SCIENCE</td>
<td>Principal Investigator</td>
<td>yes</td>
<td></td>
</tr>
</tbody>
</table>

If the above list is incomplete or incorrect, please navigate to item 2.1 and make your changes there.

24.6. **Describe the circumstances and location of the process of recruitment/consent:** *(check all that apply)*

- [x] In a private area
- [ ] In a waiting room, open ward, group, or public setting
- [x] Online, over the telephone, by mail, or via fax
- [ ] Other

24.7. **Describe all measures that will be taken during the recruitment and consent process to ensure that individuals have adequate time to consider participation and to safeguard against potential coercion and undue influence:** *(check all that apply)*

They will not be forced, threatened or coerced in any way to participate in this research, and no undue influence or other form of constraint will be used to recruit individuals to participate in this research or to retain currently enrolled subjects. *(Note: “Coercion” is the use or threat...*
25. Financial Obligation and Compensation

25.1. Financial Obligation: Describe who pays for financial obligations that the subject may incur as a result of participating in the study.

☐ All costs are paid by the sponsor or funding agency.

☐ Research costs are paid by the sponsor or funding agency. Other costs are the responsibility of the participants and/or their healthcare plans.

☐ All costs are the responsibility of the participants and/or their healthcare plans.

☐ Study drug will be provided but not the costs of preparation or administration, which will be the responsibility of the participants and/or their healthcare plans.

☐ All costs are covered by the department/division.

☐ There are no financial obligations related to participation.

☐ Other

25.2. Payment for Participation: Describe how much, if any, financial or other form of compensation will be provided to the subject/family. Describe the requisite conditions that must be fulfilled to receive full or partial compensation. Describe the proposed method of timing and disbursement. If children are involved, please specifically address how the compensation will be distributed to children.

No payment for participation.
26. Participant Privacy and Data Confidentiality

26.1. Privacy Protections: Privacy is a participant’s ability to control how other people see, touch, or obtain information about his/her self. Violations of privacy can involve circumstances such as being photographed or videotaped without consent, being asked personal questions in a public setting, being seen without clothing, being observed while conducting personal behavior, or disclosing information about abortions, HIV status, or illegal drug use.

Select the provisions to protect the privacy of the individual during screening, consenting, and conduct of the research: (check ALL that apply)

- Research procedures will be conducted in person in a private setting.
- Data will be captured and reviewed in a private setting.
- Only authorized research study personnel will be present during research related activities.
- The collection of information about participants is limited to the amount necessary to achieve aims of the research.
- Participants will not be approached in a setting or location that may constitute an invasion of privacy or could potentially stigmatize them.
- Other (specify below)

26.2. Confidentiality Precautions: Confidentiality is an extension of the concept of privacy; it refers to the participant’s understanding of, and agreement to, the ways identifiable information will be collected, stored, and shared. Identifiable information can be printed information, electronic information, or visual information such as photographs.

How will the research data/specimens be recorded? (check ALL that apply)

- Data and/or specimens will be directly labeled with personal identifying information. (Identifiable)
- Data and/or specimens will be labeled with a code that the research team can link to personal identifying information. (Coded)
- Data and/or specimens will not be labeled with any personal identifying information, nor with a code that the research team can link to personal identifying information. (Anonymous)
- Other (explain below)

26.3. How will the research data and/or specimens be protected against inappropriate use or disclosure? (check ALL that apply)

- Locked office
- Locked storage unit
- Restricted access to authorized study personnel
- Secure computer/laptop
- Individual ID plus password protection
- Encryption of digital data
- Network Restrictions
- Security software (firewall, antivirus, anti-intrusion) is installed and regularly updated in all servers, workstations, laptops, and other devices used in the study
- Restrictions on copying study related materials
- Destruction of source data immediately after data collection (to preserve anonymity of participants)
- Audio and/or video recordings will be transcribed and then will be destroyed
Audio and/or video recordings will be modified to eliminate the possibility that study participants could be identified

Photos or images will be modified to eliminate the possibility that study participants could be identified

Study personnel will sign statements agreeing to protect security and confidentiality of study information

Access rights are terminated when authorized study personnel leave the study

Not Applicable

Other (specify below)

26.4. Will coded or identified data and/or specimens be released to a third party (external to USC/CHLA)?

Yes ☐ No ☑

26.5. What will happen to the research data and/or specimens at the conclusion of the study?

(check ALL that apply)

Direct identifiers and/or the key to the codes will be destroyed upon completion of the research (all data/specimens will be stripped of identifying information and/or the key to codes destroyed, paper documents shredded, electronic files purged, electronic media securely erased).

☑ Retained for study record keeping purposes per institutional policy.

☑ Retained by the investigator for future research use.

☑ Retained for future research use (create data or tissue repository/bank).

☐ Restricted use data will be destroyed or returned to the source.

☐ No direct or indirect identifiers are being collected. The anonymous data and/or specimens will be retained at the discretion of the investigator.

This research is a clinical trial conducted under FDA regulations. Direct identifiers and/or the key to the codes will be destroyed as directed by the sponsor (IND/IDE holder) in accordance with FDA regulations.

☐ Other (specify below)

28. Risk/Benefit Analysis - Potential Benefits and Alternatives

28.4. Risks in relation to benefits:

☐ The potential benefits to the research participants justify exposure of the participants to the risks.

☑ The potential benefits to humanity justify exposure of the participants to the risks.

☐ Other (specify below)

35. Is the HIPAA Privacy Rule Applicable?

35.1. Do you intend to access, review, collect, use or disclose protected health information (PHI) in
your research? Answer yes if you intend to do any of the following:

- Look at medical records (paper or electronic) to identify potential research participants
- Look at clinic logs to identify potential research participants
- Record demographic information obtained from medical records (paper or electronic)
- Record health information obtained from medical records (paper or electronic)
- Obtain information from laboratory reports, pathology reports, radiology reports or images, or other reports from medical or mental health testing and treatment
- Obtain information from medical billing records
- Record or use medical record numbers or other information that could be used to identify an individual (review the list of HIPAA identifiers below)

☐ Yes  ☐ No

35.2. Do you intend to record data that contains any of the 18 elements defined by HIPAA as identifiers (listed below), in your research?

☐ Yes  ☐ No

- Name/Initials
- Street address, city*, county*, precinct*, zip code*, or equivalent geocodes*
- All elements of dates (except year) directly related to an individual (date of birth, admission date, discharge date, date of death)*
- Elements of date, including year, for persons 90 or older
- Telephone number
- Fax number
- Electronic mail address
- Social Security Number
- Medical record number
- Health plan identification number
- Account number
- Certificate/license number
- Vehicle identifiers and serial numbers, including license plate number
- Device identifiers and serial number
- Web addresses (URLs); Internet IP addresses
- Biometric identifiers, including finger and voice print
- Full face photographic images and any comparable images
- Any other unique identifying number, characteristic, or code*

35.3. Are you going to record only the personal identifiers marked with an asterisk (*)? If so, you may be able to obtain or use such health information from a healthcare provider for research purposes without an authorization. Under the HIPAA Privacy Rule, this data constitutes a “limited data set”. If you are creating or obtaining a limited data set, you must complete a Data Use Agreement. Attach a copy of the signed Data Use Agreement below.

Guidance

USC Template Data Use Agreement

iStar ID: UP:  Application Version Date:  Version: 1.0

39. Conflict Of Interest Information

39.1. Does the Investigator, Research Personnel or Close Relation have an ownership interest (any equity in a non-publicly traded company, regardless of value, or stock, stock options or warrants, in a publicly traded company of $5,000 or more excluding mutual funds) in:

- The sponsor of the research; or
• An entity that has a license or is negotiating a license to the intellectual property (e.g., patents) developed from this research; or
• An entity that has an economic interest in the research.

Yes  No

39.2. Does the Investigator, Research Personnel or Close Relation have a management role (such as director, officer, scientific, or technical appointment), or any other role with significant decision-making authority, in:

• The sponsor of the research; or
• An entity that has a license or is negotiating a license to the intellectual property (e.g., patents) developed from this research; or
• An entity that has an economic interest in the research.

Yes  No

39.3. Did the Investigator, Research Personnel or Close Relation receive in the last twelve months or does the Investigator, Research Personnel or Close Relation expect to receive in the next twelve months any payments for services (such as speakers fees, payments for consulting, participation on an advisory board, or assistance with protocol design) from:

• The sponsor of the research; or
• An entity that has a license or is negotiating a license to the intellectual property (e.g., patents) developed from this research; or
• An entity that has an economic interest in the research.

This does not include salary for services as an investigator/staff on the research study. Also excluded are payments from the federal government for services performed (i.e. peer review, study section participation, seminars, lectures, or service on advisory committees).

Yes  No

39.4. Does the Investigator, Research Personnel or Close Relation personally receive intellectual property rights (e.g. patents, copyrights, or royalties) directly from:

• The sponsor of the research; or
• An entity that has a license or is negotiating a license to the intellectual property (e.g., patents) developed from this research; or
• An entity that has an economic interest in the research.

This does not include royalties paid directly from USC.

Yes  No

39.5. To the investigator’s knowledge, does the Institution have financial and or intellectual property interests in the sponsor or the products used in this project? An institutional conflict may occur when a financial interest of the University has the potential to bias the outcome of research conducted by its employees or students or to create an unacceptable risk to human subjects.

Yes  No

40. Additional Supporting Documents

40.1. Attach any other documents that have not been specifically requested in previous questions.
40.2. If there is any additional information that you wish to communicate about the study include it below. Please note, this section should not be used instead of the standard application items.

99. Instructions for Submission

You have reached the end of the application. When you are sure of the content, the following steps may be taken to submit your application for review.

1. Click the "Finish" button on the top or bottom application navigator bar to return to the workspace.
2. Use the SmartForm Progress Calculator to determine that all sections of the application are filled out correctly.
3. Use the "Send Study Ready Notification" activity to send an email to the Principal Investigator and Co-Investigators with instructions for reviewing and submitting the application.
4. All listed Co-Investigators (indicated in item 2.1.) must use the "Agree to Participate" activity and answer yes.
5. Once all the Co-Investigators have agreed to participate, the Principal Investigator (indicated in item 2.1.) can submit the application by using the "Submit Application to __________", where _____ indicates the IRB you are submitting to.
6. The PI will have to check the PI endorsement box. The PI will also have to check the student endorsement box if it is applicable.
7. The application is submitted. The state indicator in the top left of the workspace will no longer display Pre Submission.
8. The PI and Study Contact Person will receive an email confirming the application has been submitted.