Larkin Community Hospital

New Protocol Submission- IRB for Human Subject Research

Center Rep: Roboam Aguirre, MD, DBA	**To be completed by IRB Office**
Date Sent to IRB:	**Protocol Number:** 3Apr2019

Instructions: In order to comply with federal regulations and with the university's IRB guidelines, the Principal Investigator (PI) is required to complete all of the following items. After completing, submit this document and all consent forms and research instruments (questionnaires, interviews, etc.) to the appropriate IRB College/Center Representative. You can find your college/center representatives using the following link: http://larkinhospital.com/site/

- If your study qualifies for center level exemption from further review, the Center Representative will exempt your study, provide you with a memo to that regard, and give you copies of the stamped, approved consent/assent form(s), if applicable. The Center Representative will log your study into the IRB database and forward a copy of the complete submission to the IRB office.
- If your study appears to qualify for expedited review, then once the Center Representative believes the submission is complete, the Center Representative will log your study into the IRB database and forward **ONE** complete submission packet to the IRB office for review.
- If full review is required, the Center Representative will log the study into the IRB database and will provide the PI with instructions for submitting 2 copies of the submission and all supporting materials (research protocol, consent/assent forms, letters of authorization, etc.) to IRB. Please note: ONLY ONE copy of all research instruments (tests instruments, interview protocols, etc.) needs to be submitted. The completed package must be received by the IRB by the last business day of the month prior to the next scheduled IRB meeting. Because mail, including express delivery, takes at least a day to be delivered within the hospital, please make allowance for this in your planning. Incomplete submissions will delay review by the IRB. The IRB reserves the right to postpone review of protocols at convened meetings due to needed revisions.

Use a word processor to complete this form. You do not need to be concerned about where page breaks fall. You are to complete all **BLUE** sections. Be sure that all pages, including any appendices or attachments, except for consent/assent forms and advertisements, are numbered sequentially. For further information, refer to http://larkinhospital.com/site/

Do **not** approach subjects about being in the research study until you have received LCH IRB approval. March 1, 2014

1. General Information

1.A. Research Project Title:

Was the Immune System of the Puerto Rican Population Affected by Post-Hurricane Maria Air Pollution?

1. B. Insert Principal Investigator's (PI) Last Name and Date of Submission in the footer.

1.C. Brief Overview (Max 250 Words):

After Hurricane Maria devastated Puerto Rico, indoor air pollution (IAP) became a public health concern. We hypothesize that chronic exposure to IAP affected the immune system of the Puerto Rican population, such as becoming more reactive to pro-inflammatory components present in IAP.

To test this, we will compare the human blood leukocytes reactivity of Puerto Ricans exposed to the post-Hurricane Maria IAP and Puerto Ricans not exposed to IAP.

1. D. Principal Investigator (PI) Information

Name	Felix E. Rivera-Mariani	Relationship to LCH	
Mailing Address (for Students)	18301 N Miami Ave, Miami, FL 33169		
Interoffice Mail Code (for Faculty/Staff)	Ext 7516	Student / Resident	
Daytime Phone	3015-760-7516	Faculty	
Alternate Phone	787-563-6862	Staff	
LCH Email Address	frivera@ularkin.org	LCH Center/College/Dept.	
Alternate Email Address	friveram@riplrt.com	College of Biomedical Sciences, Larkin University	
Degree/Academic Information	PhD (Microbiology) University of Puerto Rico	PI CITI Completion Date*	
		10/1/2018	

Please briefly describe your applicable professional, educational, employment, professional licensure, and research experience. Do NOT attach your vitae.

I am an Early-Stage Investigator with interest in providing insights of physiologically-relevant information about the interface of human health and microbial exposures by implementing human-based immunological approaches. My interest in this line of scientific research originates during my studies towards a PhD in Microbiology under the mentorship of Dr. Benjamín Bolaños-Rosero at the Department of Microbiology, School of Medicine of the University of Puerto Rico – Medical Sciences Campus. Under his mentorship, my research provided insights into the prevalence of immunological reactivity to previously uncharacterized fungal allergens endemic in the atmosphere of Puerto Rico. These findings also warranted recently published studies, in which molecular biology, biochemistry, and bioinformatics were employed to characterize these allergens.

As a post-doctoral fellow at the Bloomberg School of Public Health of the Johns Hopkins University, I further expanded my interest in human-based immunological approaches. I was co-mentored by Dr. Thomas Hartung (director of the Center for Alternatives to Animal Testing of Johns Hopkins University) and Dr. Patrick Breysse (currently the director the National Center for Environmental Health at the CDC). Among the spotlights was the further development of the human whole blood pyrogen (HWBPT). In this assay, which was developed in Europe by Dr. Hartung as an animal-free substitute for medical devices and toxicological testing, immune cells react to stimuli in their natural environment (peripheral blood) in an *in-vitro* setting (Hoffman et al. 2005). By measuring immunological biomarkers after stimuli exposure, the utility of the assay was evident when employed to assess the pro-inflammatory potential of indoor air pollution (Bose et al. 2016), potentially-allergenic fungal spores (Rivera-Mariani et al. 2013, 2014) and different microbial compounds (Hasiwa et al. 2013). For my research efforts with this assay, I received the *Lush Young Researcher Award* in 2012 (London, UK) from the Lush Retail Ltd and the Ethical Consumer Research Association for expanding the HWBPT into new areas of research. This immunological assay was also employed in a collaborative RO1 (3R01ES018845-04S1, PI: Nadia Hansel**).**

In addition to my scientific research training and experience, I gained and followed upon on intensive training in computational biology and data science approaches. This computational training has expanded my scientific spectrum of research and has opened collaborative projects to identify gene expression (transcriptomics) and protein profiles (proteomics), and elaborate predictive statistical modeling in aerobiological studies.

1. E. Co-Investigators (Co-I) Information (including faculty advisers)

	Co-Investigator 1	Co-Investigator 2	Co-Investigator 3
Name	n/a	n/a	n/a
Mailing Address			
Contact Phone Number			
Email Address			
Degree/Academic Information:			
CITI Completion Date*			

Please briefly describe applicable professional, educational, employment, professional licensure, and/or research experience for all co-investigators. Do NOT attach vitae.

1. F. Research Assistant Information (if applicable)

	Research Assistant 1	Research Assistant 2	Research Assistant 3
Name	Hayat Srour	Shandra Bellinger	Joshua Baguley
Mailing Address	18301 N Miami Ave, Miami, FL 33169	18301 N Miami Ave, Miami, FL 33169	18301 N Miami Ave, Miami, FL 33169
Phone Number	313-806-5186	301-728-1383	832-795-6038
Email Address	hsrour@riplrt.com	sbellinger@riplrt.com	jbaguley@riplrt.com
CITI Completion Date*	12/28/17	01/09/18	12/14/17

1. F. Research Assistant Information (if applicable)			
	Research Assistant 4	Research Assistant 5	Research Assistant 6
Name	Ruslan Fomenko	Ariel Stateman	Summer Pellechio
Mailing Address	18301 N Miami Ave, Miami, FL 33169	18301 N Miami Ave, Miami, FL 33169	18301 N Miami Ave, Miami, FL 33169
Phone Number	757-672-1898	630-276-8380	
Email Address	rfomenko@riplrt.com	astatemen@riplrt.com	sxp1223@rit.edu
CITI Completion Date*	01/07/18	12/14/18	1/23/2019

*NOTE: CITI must have been completed within the last 3 years. If a member of the research team is affiliated with another institution, please include a copy of that individual's training certification.

1. G. Funding Information				
Funding status	Unfunded		Funding Applied For	Funded
			X	
If you indicated "Funded" or "Funding Applied For," complete the following.				
Source of Funding	Experiment.com crowdfunding platform			
Project Title (if different from above)				
Principal Investigator (if different from above)				
Type of Application	Grant	Subcontract	Contract	Fellowship
	x			
Award Amount:	$2320			

1.H. Management of Conflict of Interest

Read the financial conflict of interest policy at http://larkinhospital.com/site/

PI Initials	FERM

I certify that I, as PI, have read this policy, and have verified that my co-investigators and research assistants also have read this policy.

For studies that are funded by a governmental agency (any federal, state or local governmental entity that has promulgated regulations or policies requiring investigator financial disclosure or requiring institutional conflict of interest policies relating to award of grants or contracts) read the Office of Sponsored Program's Financial Conflicts of Interest in Sponsored Programs policy.

I certify that I, as PI, have read these guidelines, and have verified that my co-investigators and research assistants also have read these guidelines.

PI Initials	FERM

Yes	No
	X

Do any investigators have a significant financial interest, as defined in the above referenced policy, in relation to this study?

If yes, please describe the nature of the conflict of interest below

If you answered yes, please be sure to include the following statement, or a similar statement, within the description section of the consent forms: "The principal investigator and/or co-investigator(s) of this research study have a significant financial interest as it relates to this study." Continue, describing the conflict in the consent/assent documents.

1.I. Dates and Phases of Study

Proposed Start Date		
[X] Shortly after IRB approval	Other (list date)	

Proposed Duration of Research (including analysis of the results)	
One year or less [X]	Other (describe, please note minimum annual continuing review required)

Yes	No
[ ]	[X]

Is this a multi-part study?

If "Yes," please note that procedures used in later phases may affect the review status of this study. Briefly describe the later stages.

1. J. Multiple Site Information

Yes	No
[X]	[ ]

Will the study be conducted at an LCH location? **Larkin University**

If "Yes," provide the location within LCH, e.g. department or clinic.

Larkin University College of Biomedical Sciences

Will the study involve any LCH faculty, staff or students as subjects?

Yes	No
[X]	[ ]

Will the study be conducted at a non-LCH location?

Yes	No
[ ]	[X]

Will any of the activities be done online or via telephone (e.g., completion of surveys, delivery of instructional content)?

Yes	No
[ ]	[X]

If "Yes", for the Internet based activities, will these be done via a secure site?

Yes	No
	X

If "Yes," please complete the following for the non-LCH sites.
Include these sites on the consent form in the "site information" section.

	Site 1	Site 2	Site 3
Site Name			
Address			
Phone Number			

You will need documentation of permission to conduct the research at non-LCH sites. Attach the permission letter(s) or IRB approvals to this document.

1.K. Cooperative Research

Cooperative research projects are those that involve more than one institution or when an investigator is employed at or is an agent of an institution other than LCH, (For more information, see **http://www.hhs.gov/ohrp/humansubjects/guidance/engage08.html**). Each participating institution is responsible for safeguarding the rights and welfare of human subjects and for complying with all regulations.

Does this research involve cooperative research?

Yes	No
	X

Has this proposal been submitted or will the proposal be submitted to another Institutional Review Board (or authorizing individual, entity, or ethics review board) for review?

Yes	No
	X

If "Yes," please complete for each site. Please attach documentation of approval.
(Copy the section of the table and add if there are multiple sites.)

Name of Institution	

IRB/Administrative Decision (check applicable)

Approved	Submitted (not yet approved)	Not yet submitted	LCH IRB approval required prior to submission

Date of Review	Contact Person / Phone Number	Level of Review (if IRB Reviewed)		
		Exempt	Expedited	Full

2. Subject/Participant Information

2.A. Overview of Proposed Subjects/Participants
(complete **all** that apply and provide maximum number proposed within each category):

Subject Group	Fetus in Utero/ non-viable fetuses/ abortuses	Newborns or Infants	Children (aged 2-6)	Children (age 7-12)	Adolescents (aged 13-17)	Adults (18+)	Pregnant Women	Adults with Guardians
Mark X for each proposed subject type						X		
# of Proposed Subjects*						20		

Please briefly describe your potential subjects:

Participants of interest include larkin community members who lived in Puerto Rico (PR) before hurricane Maria and participants who traveled to PR after the hurricane.

*By proposed subjects, the IRB means subjects who will consent to be in the study and begin the study activities.

2. B. Subject Vulnerability

Yes	No
	X

Do any subjects have limited decision-making autonomy, have communication problems that would limit ability to dissent to study procedures, belong to a group that is vulnerable to coercion, or belong to a group defined by regulation as requiring greater care?

If you indicated "Yes", please mark with an X next to each applicable category in the column to the right and complete the remainder of this section	
Prisoners	
Pregnant Women	
Cognitive impairment or emotional problems that potentially limit decision making	
Communication impairments that may preclude communicating a decision to discontinue participation or refuse participation	
Students of the investigator or investigator's department	
Employees of the investigator or investigator's department	
Children (minors)	

Terminally ill ☐

Other (specify):

If you indicated any of the above, please justify your rationale for including these subjects.

Yes	No
☐	X

If you are using potentially vulnerable subjects as described above (infants, children, pregnant women/fetuses, terminally ill, decision-impaired, communication-impaired, students/employees, or prisoners), does the research create greater than minimal risk?

If your subjects have a vulnerability that arises from their being students in your class or department, you will be asked for more information in Section 3.G. If the subjects have one of the other vulnerabilities, please describe proposed safeguards to protect vulnerable subjects.

If not evident from the researcher qualification information in 1.D. or 1.E., please describe the researcher(s) qualifications for working with vulnerable subjects

2. C. Study Design and Methodology

Part 1 – Purpose

Please briefly describe the **purpose** of your study. Note: Examples of study purposes are "to determine if a new reading intervention program improves 4th graders' reading scores" or "to survey patients on their perception of physical therapy services".

To determine if Puerto Ricans exposed to the post-Hurricane Maria air pollution are now more immuno reactive to air pollution than Puerto Ricans that moved to the US before Hurricane Maria affected Puerto Rico.

Part 2 – Goals and Justification

Briefly elaborate on the main **goals and justification** for the study. Summarize the background, rationale, nature, and significance of the proposed research. Include a brief overview of your prior research in the area, or literature that supports the need for this study. This section should be a brief overview, and typically is not more than a few paragraphs in length. You will be asked about procedures and instruments later in the submission.

We hypothesize that immune system of the Puerto Rican population exposed to post-Hurricane Maria indoor air pollution (IAP) is more reactive than those not-exposed (Puerto Ricans not living in the affected areas). To test this hypothesis, We will be challenging human blood leukocytes of Puerto Ricans to 50 indoor air samples to determine if the immune system of Puerto Ricans exposed (10 subjects) to post-Hurricane Maria IAP is more reactive than those not exposed (10 subjects). We will be measuring, via ELISA assay, the levels of the pro-inflammatory biomarker interleunkin-1beta induced in human blood immune cells from volunteer Puerto Rican subjects after challenge to the indoor air samples. The indoor samples were collected for an ongoing study related to Hurricane Maria.

Our group PI, Dr. Felix Rivera-Mariani, is an expert in the field and understanding the long-term toll pyrogens play on respiratory health. Our group is currently conducting a longitudinal study in Puerto Rico, examining the inflammatory response in subjects with water-damaged homes caused by hurricane Maria. IL-1b is a potent proinflammatory cytokine that plays a major role in inflammatory responses. Its presence has numerous effects on the body ranging from autoimmune conditions, hematologic abnormalities, pain, neurologic conditions, infections, allergic reactions and vascular diseases. Studying the presence/levels of IL-1b in those that have been exposed to harsh living conditions, like post hurricane, can provide insight into the role the environment plays on one's health. It can lead to further research looking into possible predispositions, exploring preventive measures, and immune thresholds that have the ability to cause disease by exploring length of exposure to the environment. Being able to compare the levels of IL-1b after a hurricane which causes a change in the type and population of allergens, water conditions and hygiene will open the door for us to explore many other lingering questions. Using the human whole blood pyrogen test (HWBPT), we are able to quantify and examine the inflammatory response in these homes. This is the same method we plan to approach the transient population of Puerto Ricans.

Part 3 – Steps in the Research Study

In the box below, please outline in detail the **steps in the research study** in order as they will occur after consent has been secured. If there are different requirements for different groups/types of subjects within the study, please separate out the steps per group. Indicate how long the subject spends completing the different steps/procedures. Be specific about the tests given and/or treatments used, when they will occur, and their frequency.

After IRB approval, we will begin recruitment of volunteers. We will recruit 20 volunteers: 10 who lived in PR before and 10 who lived in PR during the hurricane, and now (both groups) are living in the US (South Florida region). From these volunteers, we will draw blood and challenge their human blood immune cells with the indoor air samples are already available as part of another study. The immuno-reactivity will be determined based on the human blood leukocytes to release IL-1beta biomarker, which will measured with enzyme-linked immunosorbent assay.

Part 4 – Sources of Data Information

Are you using questionnaires, tests, instruments, or forms?

Yes	No
	X

If "Yes", list them below and include a copy of each as appendices.

Yes	No
	X

Do you plan to use any data from records or archives?

If "Yes", please describe (such as data originally created for non-research purposes or data created as a result of a previous study).

Yes	No
X	

Do you plan to use any de-identified data?

If "Yes", please describe the data and how it will be de-identified.

Safe Harbor regulations require that no parts or derivatives of any of the listed identifiers be disclosed in healthcare data. All the data and images that will be collected in the proposed study will be de-identified following the guidelines and stipulations mandated by Health Insurance Portability and Accountability Act (HIPAA) (Methods for De-identification of Protected Health Information in Accordance with the Privacy

Rule). Specifically we will use the ***"Safe Harbor" method.*** The following identifiers will be removed:

(A)Names,

(B) All geographic subdivisions smaller than a state, including street address, city, county, precinct, ZIP code, and their equivalent geocodes, except for the initial three digits of the ZIP code if, according to the current publicly available data from the Bureau of the Census:

(1) The geographic unit formed by combining all ZIP codes with the same three initial digits contains more than 20,000 people; and

(2) The initial three digits of a ZIP code for all such geographic units containing 20,000 or fewer people is changed to 000

(C) All elements of dates (except year) for dates that are directly related to an individual, including birth date, admission date, discharge date, death date, and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older,

(D) Telephone numbers,

(E) Fax numbers,

(F) Email addresses

(G) Social security numbers

(H) Medical record numbers

(I) Health plan beneficiary numbers,

(J) Account numbers,

(L) Vehicle identifiers and serial numbers, including license plate numbers,

(M) Device identifiers and serial numbers,

(N) Web Universal Resource Locators (URLs),

(O) Internet Protocol (IP) addresses,

(P) Biometric identifiers, including finger and voice prints,

(Q) Full-face photographs and any comparable images,

(R) Any other unique identifying number, characteristic, or code, except as permitted by paragraph (c) of this section [Paragraph (c) is presented below in the section "Re-identification"]

3. Additional Study Information

3. A. Clinical Testing

Food and Drug Administration
Investigational Drugs and Devices

Does the study involve the use of an investigational drug?

Yes	No
	X

If "Yes", has an Investigational New Drug application been submitted for the drug?

Yes	No
	X

Does the study involve the use of an investigational device?

Yes	No
	X

If "Yes", has an Investigational Device Exemption (IDE) been, or will be, secured prior to the start of the study?

Yes	No
	X

Does the study use any device (either as a part of the experiment or to collect data) that has not received FDA approved for clinical/medical use or is being used in a manner not consistent with its cleared/marketing status?

Yes	No
	X

If "Yes", please describe the device and how its use differs from its approved status by the FDA.

Clinical Procedures

Does the study involve the use of any procedure that is not used in routine clinical practice?

Yes	No
	X

If "Yes", please list the procedures.

3. B. Sensitive Information

Yes	No
	X

Are you asking questions about sensitive issues, such as illegal activity, sexual history, or anything else that, if made public, could jeopardize a person's reputation, employability, safety, or quality of life?

If "Yes", please describe the information.

Yes	No
	X

Does the study involve the collection of data from voice, video, digital, or image recordings made for research purposes?

If "Yes", please describe the procedures associated with these recordings.

3. C. Non-English Speaking Participants

Will the study involve non-English speaking participants?

Yes	No
	X

Will the study require translation of consent forms?

Yes	No
	X

If you answered "Yes," please specify the language(s) that the consent forms will be translated in to:

If you are including non-English speaking participants, when you complete section III.H., please discuss how you will ensure that the participants understand the study, including the use of a qualified translator to provide oral consent information.

3. D. Subject Compensation

Will your subjects receive any payments, incentives, or gifts?

Yes	No
X	

If "Yes," please indicate the types of compensation. Otherwise move on to section E.

Monetary Payment	Gift	Extra credit (Students) or Workplace Incentive (Employees)
	X	

Other incentive

Please describe:

Describe the payment(s)/gift(s)/incentive(s), and if it is a gift, estimate its monetary value. Indicate whether all participants are given the payment/gift/incentive, or if only some are eligible. (Note: the value of the payment/gift/incentive should not be so significant that it might compromise the subject's good judgment.)

Subjects will receive a gift card amounting to $15 for participating in study.

Describe when the subject will receive the payment/gift/incentive, and whether the amount differs depending upon whether different portions of the study are completed or is limited if the subject discontinues participation during the study.

Participants will receive gift following completion of blood draw.

3. E. Inclusion / Exclusion Criteria for Subjects

Describe the inclusion and exclusion criteria for the proposed subjects. Please list the criteria in bullet or outline format rather than narrative. If the study limits participation based on gender, age or race, please justify the exclusion criteria. (Subject protection and appropriate study design may require specific inclusion or exclusion criteria, but the IRB does not permit subject selection that is not equitable or prevents a subpopulation from benefiting from the scientific discoveries of the study.)

Inclusion Criteria

1. Puerto Rican population who lived in Puerto Rico before or during the Hurrican Maria, and now are living in the South Florida region

2. Participants that are 18 years or older
3. Not pregnant
4. No history of active infections or chronic conditions

Exclusion Criteria

1. Pregnant females
2. less than 18 years old
3. Never lived in Puerto Rico

3.F. Subject Recruitment

How will you recruit subjects (approach/invite/or asks people to be in your study)?

Subjects will be recruited through flyers posted within Larkin University and verbal communication via non-profit Puerto Rican organizations and Larkin University.

Recruitment Advertisements, Fliers, and Letters

Are you using any letters, fliers, or advertisements?

Yes	No
X	

If you answered yes, please list the type(s) below and attach a copy of the proposed materials as an appendix (do not copy and paste the flyer into this form).
(Note: Materials should list "Larkin Community Hospital".)

Flyer

3. G. Potential for Coercion in Subject Recruitment

Are any of the subjects a student or advisee of the PI or a Co-I?

Yes	No
	X

Yes	No
	X

Does the PI or a Co-I serve in any capacity (e.g., administrative, therapeutic) that might affect a subject's willingness to participate?

If "Yes" to either of the above, then describe the relationship of the subjects and investigator.

If you answered yes, please read the LCH policy about use of students in research.
http://larkinhospital.com/site/

Are any of the subjects employees of, or report to, the PI or a Co-I?

Yes	No
	X

Are any of the subjects a patient of the PI or a Co-I?

Yes	No
	X

Are any of the subjects a patient within a PI or a Co-I's clinical practice?

Yes	No
	X

Are any of the subjects informed about the study by their doctor / clinician?

Yes	No
	X

If you answered "yes" to any of the questions in this section (3.G.), please describe how you will ensure that the subjects will feel free to decline participation without fear of reprisal. If the subjects are patients, how will you prevent "therapeutic misconception" (the mistaken belief that when a care provider provides information about a study, it means that the provider thinks that study participation will benefit the patient).

If you are providing any incentive to the student/employee subjects, discuss whether there is a mechanism for students / employees to receive the incentive by doing something other than participating in the research project (see http://larkinhospital.com/site/)

3. H. Informed Consent

Part 1 – Consent Process

Informed consent is a process that begins with advertising or telling potential subjects about your study, continues as the investigator or staff provides details to potential subjects via dialog, and is formalized by the signing of the consent.

Note: Minors must have consent of their parents or guardians before you can approach the minor about participating in the study.
Note: Allow as much time as possible and feasible for the subject to think about whether to enroll in the study. Generally, the greater the study risks, the longer the decision period.

Please overview the steps in the consent process in your research study. If there is more than one group of subjects, separately describe the process for each group.

Participants of the study will be fully informed of the details and purpose of the study including the benefits, risks, form of compensation, and the right to stop the study at any time. We will not be collecting identifiable information on the participants. Each participant go through the inclusion and exclusion questionnaire and instructed to read a consent form entirely then sign in.

Part 2 – Consent Process and Document Waiver/Alteration Information

In most cases, subjects need to participate in a meaningful consent process and receive a consent/assent form that documents agreement to participate in research. However, in a few cases the subject's confidentiality is protected by waiving/altering consent procedures or the requirement for signed consent forms. Please read the IRB's policy on informed consent for explanations, including what the IRB must demonstrate to permit waiver or alteration (http://larkinhospital.com/site/). Please note, however, that while your study may qualify for waiver or alteration, that determination is at the discretion of the IRB.

One case where a signed informed consent form is NOT used is when a researcher is only reviewing existing/archival data that were collected for non-research purposes. If the data are obtained from the records by someone with authorization, and the data are de-identified, then it may be appropriate not to ask subjects (those whose data you are collecting) to provide consent, because the research involves no more than minimal risk, the waiver or alteration will not adversely affect the rights or welfare of subjects, the research could not practicably be carried out without the waiver or alteration, and, when appropriate, the subject will be provided pertinent information about participation. (NOTE: If your study has other procedures that require interaction with subjects or prospective collection of data, it is unlikely that waiver or alteration of consent procedures or the signing of consent forms would be appropriate.) If this describes your study, then you may request a waiver of the requirement for informed consent and the documentation of signed consent.

If you think this applies in your study, please describe your rationale.

Another situation involving waiver or alteration of the requirement to obtain a signed consent form is when

the research only entails conducting anonymous surveys that are not intrusive. If there is no way that the subjects' responses could be linked to them, then waiving the requirement for a signed consent form would minimize a risk to their confidentiality and privacy because the only record linking the subject and the research would be the consent form. If the principal risk would be potential harm resulting from a breach of confidentiality and the research presents no more than minimal risk to subjects and involves no procedures for which written consent is normally required outside of the research context, then the elements of informed consent are put into the survey itself. The person indicates his/her voluntary participation by completing the survey after being advised about the study and voluntary nature of his/her participation.

If you think this applies in your study, please describe your rationale.

There may be other cases where you would wish to ask for a waiver or alteration of informed consent or signed consent documentation.

If you are seeking a waiver or alteration, please describe your rationale.

Part 3 – Consent and Assent Document Information

Typically, you are asked to use the LCH format consent and assent forms. However, if this is cooperative research, or sponsored research that requires the use of a different template or model, you may use their format.

I will use LCH format consent/assent forms	x
I will be using another institution's format for consent/assent forms (NOTE: Please review the other institution's consent forms and the LCH requirements to be sure that all of the LCH requirements are present. You may also want to discuss the consent forms with your college/center representative)	
As noted above, I am requesting a waiver/alteration of consent and/or signed consent form requirements	

If you have different procedures for different groups of subjects, you will need a separate consent and/or assent form for each group. If the reading level of different groups of subjects differs, this may also require you to have different consent and/or assent forms (e.g. young children vs adolescents). If your subjects are children, you will also need parental consent.

What is the total number of consent/assent form types that you plan to use?

1

If using more than one consent form, create a list below that describes the different forms that you will be using (e.g. 1. Teacher consent form, 2. Parent consent form, 3. Assent form for children age 7-12, 4. Assent

form for adolescents).

Include copies of the consent / assent forms. When you attach the consent forms, put them in this order. Please note that the IRB prefers that the consent document be written using the simplest language possible, and strongly recommends the question and answer format (see http://larkinhospital.com/site/) Consent Form [Readability Score: Grade 6]).

3. I. Protected Health Information Use

Are you obtaining any data from the subject's medical record?

Yes	No
	X

Are you asking the subject about his or her health information, and doing so in a clinic or entity that would normally be subject to HIPAA regulations on protected health information?

Yes	No
	X

If you answered "Yes" to either question, continue. Otherwise go on to section 3.J.

Please review the LCH HIPAA research policies available http://larkinhospital.com/site/ for more information.

LCH IRB will NOT reviews separate HIPAA authorizations for research. It is the principal investigator's responsibility to use the correct HIPAA authorization as outlined in the aforementioned policy. In instances where the HIPAA authorization must be a part of the informed consent form for research, the LCH IRB will review the compound consent.

Specify the exact data to be gathered (e.g., weight, blood pressure, IQ score, diagnosis, depression rating, number of treatments, etc.).

Which procedure are you proposing to use? (Check)	
I will obtain the subject's authorization to obtain the protected health information via the LCH Authorization for Use and Disclosure of Protected Health Information in Research (research activities will be occurring at an LCH).	
I will obtain the subject's authorization to obtain the protected health information via the authorization for use and disclosure of protected health information in research provided by the non-LCH covered entity.	
The protected health information data are a fully de-identified data set (data obtained without recording any patient information, with the data accessed by an employee of the institution).	
The data are part of a limited data set agreement as defined by the Office of Human Research Protections. (Attach a copy of the agreement.)	

If part of a limited data set agreement, what is the justification that confidentiality is protected?

I have a waiver provided by a duly constituted privacy board. (Attach a copy of the waiver.) ☐

HIPAA Research Authorization

Yes	No
☐	☐

If the research is to be conducted at an LCH clinic, have you created a HIPAA authorization form as outlined in the HIPAA Research Policy No. 1 (http://larkinhospital.com/site/

and in keeping with the Instructions for Preparing the Authorization For Use and Disclosure of Protected Health Information in Research Form and the model form provided (http://larkinhospital.com/site/

Please note; do NOT submit a copy of the HIPAA authorization form if you are following the model noted in the aforementioned policy.

If the research is to be conducted at a non-LCH covered entity, have you reviewed the HIPAA Research Policy No. 6: Guidance on Research at Outside Entities (http://larkinhospital.com/site/)?

Yes	No
☐	☐

Researchers are advised to discuss the proposed research with the applicable HIPAA privacy officer at the non-LCH covered entity.

Does the researcher sponsor or cooperating agency require the incorporation of the HIPAA authorization within the consent document (Compound Consent)?

Yes	No
☐	☐

If yes, please briefly indicate who requires that this be in the informed consent document.

Please note, consent forms that include the HIPAA authorization may need approval from the university

Office of Corporate Compliance.

3. J. Student/Academic Information Use

Are you obtaining any data from the subject's academic records?

Yes	No
	X

If you answered "Yes", continue. Otherwise go on to section K.

Specify the exact data to be gathered (e.g., GPA, standardized test score, IQ score, medical/psychological information stored in academic files, attendance records, disciplinary records, etc.).

Specify how you will obtain the data.

Which procedure are you proposing to use? (Check all that apply)

I will obtain the subject's consent to obtain the academic information. ☐

The academic information will be a part of a fully de-identified data set (data obtained without recording any subject information, and provided to you in keeping with the institution's policies and the Federal Educational Rights and Privacy Act [FERPA]). ☐

3. K. Risks, Discomforts, & Inconveniences

In this section, discuss all potential risks (physical, economic/financial, legal, psychological, social, etc.), discomforts, or inconveniences to the subjects.

- All studies using identifiable subject information must address the issue of possible loss of subject confidentiality
- Some possible risks include physical, psychological or emotional harm, breach of confidentiality, and invasion of privacy.
- Discomfort includes anticipated risk for mild physical or emotional pain.
- Study inconveniences include loss of time or pay.

Each risk, discomfort and inconvenience should be addressed individually in the following format (use the tables provided and copy if the study presents more than 3).

- List each risk individually
- Discuss likelihood: How likely is it that this risk/discomfort or inconvenience will occur? This is usually classified as minimal, moderate, or high.
- Discuss magnitude/duration: How dire is the risk/inconvenience/discomfort, and if it occurs, how long do you expect that the subject will be affected?
- Discuss risk minimization: Describe the procedures undertaken to minimize the risk that this specific risk/discomfort/inconvenience will occur.

Risk/Discomfort	No major risks or discomforts
Likelihood	Participation in this study would involve donating blood taken by venipuncture. Drawing blood (Venipuncture) is the most common invasive medical procedure performed. While venipuncture is considered to be reasonably safe, complications can occur as a result of venipuncture even when a small amount of blood is withdrawn. The most common complications of venipuncture include bruising. Serious complications even though they are rare include sweating with low blood pressure and fainting.
Magnitude/Duration	15 minutes
Risk Minimization	A trained phlebotomist will be taking blood

Risk/Discomfort	
Likelihood	
Magnitude/Duration	
Risk Minimization	

Risk/Discomfort	
Likelihood	
Magnitude/Duration	
Risk Minimization	

One way in which confidentiality is partially protected is to destroy study documents containing identifiable information when they are no longer needed. The IRB requires that study materials be kept for a minimum of three years from the end of the study to permit study auditing; you may elect to keep them for a longer period of time and study sponsors may have their own data retention requirements. Please indicate when and how you plan to destroy data that contains identifiable subject information, such as consent forms, lists that link subject identity to data coding, or raw data containing subject names.

Study materials will be kept for at least 3 years from the end of the study and then destroyed using a HIPAA compliant shredded. Date of destruction, notation that the record was destroyed in accordance with the retention policy; and signature of staff person performing the shredding will be obtained. All electronic records saved in a computer or external drives such as USB will be permanently deleted.

3. L. Benefits to Subjects

In this section, discuss all direct benefits of the study to participants. This does not include "helping research" or other generalities, nor does it include compensation for participation. Some examples of benefits include receiving free treatment, receiving a list of reputable local services, or obtaining tutoring. The value of any such benefits should be listed as well. If there are no direct benefits to the participants, this should be indicated.

Are there any direct benefits to the research participants?

There are no direct benefits to study participants [X]

This study provides benefit to, or is likely to benefit, the participants [ ]

List/describe each benefit

"Participation in this study will not offer any direct benefit to participants or their health, but may contribute to scientific knowledge about the health of the human immune system following an atmospheric phenomenon. Because drawing blood is a routine medical procedure, participation in this study presents only a minimal risk to participants or their health. Participants will not be notified of any findings related to their blood sample because it will not be linked to their identifying information."

3. M. Data Analysis Plan

Please describe preliminarily proposed data analysis procedures.

The whole blood of participants will be exposed to various allergens and the inflammatory response will be measured by and quantified by ELISA test. The test will be run on groups of individuals from Puerto Rico and groups from contiguous USA. The data collected from the ELISA tests will be compared across the two groups and statistical tests will determine if there is a significant difference between the populations.

3. N. Scientific Benefit

Briefly discuss how generalization of the information obtained from this study will be scientifically useful, or useful to your research site.

The information obtained from the study will provide further information into the behavior of immunologic responses before and after extended exposure to various allergens. This will help the people of Puerto Rico in preparation and treatment for future natural disasters.

3. O. Risk/Benefit Ratio

To be approved, a study needs to have greater benefits than risks. Why do you believe this study has a positive benefits-to-risks ratio?

The study is expected to have a positive benefits-to-risk ratio as the risks to those participating in the experiment are quite low. The method of drawing blood is simple and when performed by a certified phlebotomist, there is a low probability of error. Other potential risks for the participant would be a breach in confidentiality, however through the guidelines laid out in the proposal, this too would have a low probability of occuring.

The benefits of the study would come in many forms. The determination of the effects of allergens on different populations could lead to a better understanding of the immune system. It would also allow for the development of systems that would limit health hazards following a natural disaster.

3. P. Safety Monitoring Plans

All researchers are required to report adverse events and unanticipated problems in keeping with the LCH IRB policy (http://larkinhospital.com/site/).

Yes	No
	X

Studies that entail significant risk to subjects, such as randomized controlled drug trials, may warrant safety monitoring by an outside safety board. Does your study utilize a Data Safety Monitoring plan?

If "Yes," please describe the safety monitoring plans. Please specify if the study will be monitored by the investigators, sponsors (if applicable), or a Data Safety Monitoring Board (DSMB). Sponsored studies may reference an attached Investigator Brochure.

3. Q. Other Information

If there is other information about this study that is required in order for those reviewing the study to fully understand the study, its risks and benefits, please describe below.

3. R. Principal Investigator Assurance and Obligations

I certify that all information provided in this submission (including any supporting documents) is a complete and accurate description of the proposed study. I agree to the following:

PI Initials	FERM

This study will be conducted in the manner described in this submission and will not be implemented (including subject recruitment or consenting) until all applicable IRBs have granted permission to conduct the research. No changes to this study will be implemented until an amendment form has been submitted and approved by the IRB.

PI Initials	FERM

If the IRB approves this study via expedited or full procedure, I will submit for continuing review as stipulated in the approval letter. If the study or data analysis will exceed the approval period, I will submit a Submission Form for Continuing Review of IRB Approved Studies in a timely manner (well in advance of the renewal date). I understand that study activities may not continue past an approval period.

PI Initials	FERM

I will provide a copy of the signed consent form to the subject or patient, if applicable.

I will retain all signed informed consent documents and study-related records for a minimum of three (3) years (or longer as stipulated by funding agencies) from the date the study is concluded.

PI Initials	FERM

I will report in writing any serious adverse events to the IRB within 24 hours and all other adverse events and unanticipated problems within 5 working days.

PI Initials	FERM

PI Initials	FERM

I will provide participants with any significant new information obtained during the course of the study and submit reports of new information to the IRB as a Study Amendment.

PI Initials	FERM

If my study has been approved at the Expedited or Full Review levels, I will report to the IRB when this study has closed (no further data collection or analysis). This report will be provided no later than 30 days after the end of the study via the IRB Closing Report Form.

Principal Investigator's Signature: ____Felix E. Rivera-Mariani_____Date: _____1/27/2019_____

3.S. Co-Investigator Assurance and Obligations (for Student PIs)

If this study is for the completion of a degree requirement, the thesis adviser or dissertation chair must sign the attestation below.

- All departmental approvals by the student's committee (if applicable) and chair or thesis adviser have been completed.
- I accept that the University and IRB consider the faculty advisor's responsibility to be equal to that of the student in regard to
    - The quality of the research design AND the accuracy of the protocol

- The appropriateness of the recruitment methods, the design of the process for informing the subjects about the nature of the study, and the process of obtaining informed consent
- The readability, accuracy, and format of the informed consent/assent document(s) and the explanation of all informed consent procedures.

My signature below attests that I have read this submission in its entirety and believe that it is accurate, complete, appropriate, and adheres to the principles of the Belmont report and that all departmental approvals by the student's committee have been completed.

Chair/Adviser's Signature: _____ Date: _____