



Manuscript Proposal and Dataset Request Form

Date of Request:

MM	DD	YYYY

Original Data Request: Yes No

Additional Data Request: Yes No

Manuscript Title or Purpose

Approved manuscript proposal #: This number is assigned upon approval of manuscript proposal.

Agreement of Data Distribution (ADD) Included with Request: Yes No

Certificate of Confidentiality (C-CERT) Included with Request: Yes No

ADD Previously Submitted: Yes No

C-Cert Previously Submitted: Yes No

Investigators: Please list the principal investigator and co-authors of the approved manuscript proposal. The ESPINA study core should be notified of changes in titles and authors.

First author:		E-mail:		Phone:	
Co-authors:					
Statistical Programmer:					

*ESPINA Representative		E-mail:	
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*A representative is an ESPINA Investigator working with you on this manuscript.

Provide a summary of the proposed work/manuscript (200 words max)

1. Background
2. Main Study Questions and Hypotheses
3. Brief analytic plan
4. Timeline of work

Expected date of completion:

MM	DD	YYYY

COMPLETE THIS PAGE ONLY IF DATA IS BEING REQUESTED.

Identify data years to be used in proposal by typing an "X" in the box to the "Right" of exam.

	Year 0 (2008)	Year 8 April (2016)	Year 8 Jul- Oct (2016)
Data:	Exam 1	Exam 2	Exam 3

Data requested: Provide a list of variables and exams: (may be submitted as a separate page).

Comments:	

Submit Request to:

Jose R Suarez (jrsuarez@health.ucsd.edu)

Principal Investigator



**The Secondary Occupational Pesticide Exposure among Children and Adolescents (ESPINA) Study
CONFIDENTIALITY CERTIFICATION (C-CERT)**

ALL INDIVIDUALS WITH ANY ACCESS TO DATA OR REQUESTING DATA ACCESS OF THE SECONDARY OCCUPATIONAL PESTICIDE EXPOSURE AMONG CHILDREN AND ADOLESCENTS (ESPINA) STUDY MUST READ, SIGN AND DATE THIS CONFIDENTIALITY CERTIFICATION.

Investigators are responsible for ensuring that all individuals affiliated with the ESPINA Study (currently or in the future) sign the Confidentiality Certification at the time the individuals start working with Study materials or products.

Certification:

As an investigator, employee of, consultant to, or fellow/student involved with the Secondary Occupational Pesticide Exposure among Children and Adolescents (ESPINA) Study funded by the National Institute of Environmental Health Sciences (NIEHS), I am aware of the confidential nature of data on research participants maintained by the Study, and of the necessity for maintaining that confidentiality.

I agree not to transfer or disclose any confidential data, or any information about individual ESPINA Study participants, except as necessary for data/safety monitoring or programmatic management, or as agreed by the ESPINA Study, during my responsibilities at work or in private, either during or after my affiliation with the ESPINA Study. I agree not to transfer any ESPINA data to individuals outside the ESPINA Study Group without the written permission of the ESPINA Study core investigators. I agree to not transfer ESPINA datasets via email. Furthermore, I agree to return all ESPINA data to the Principal Investigator or delete/destroy all ESPINA data upon termination of my affiliation with the Study, or maintain such data as agreed with the ESPINA Study.

Name: _____

Signature: _____ Date (MM/DD/YY): _____

ESPINA Principal Investigator: _____

Signature: _____ Date (MM/DD/YY): _____



**The Secondary Occupational Pesticide Exposure among Children and Adolescents (ESPINA) Study
Agreement for Data Distribution (ADD)**

THIS DOCUMENT SHOULD BE FILLED OUT ONLY IF REQUESTING DATA.

The undersigned parties hereby enter this Agreement of Data Distribution (ADD).

A. INTRODUCTION

The Secondary Occupational Pesticide Exposure among Children and Adolescents (ESPINA) Study is cohort study of children aimed at understanding the associations between subclinical exposures to pesticides and child development.

To protect the confidentiality and privacy of ESPINA participants and their families, investigators granted access to Data and Materials must adhere to the requirements of this ADD. Failure to comply with this ADD could result in its termination, denial of further access to ESPINA resources.

The undersigned parties entering this ADD include: the Recipient and Recipient's Principal Investigator (defined in the next section) and an ESPINA Study representative, on behalf of the ESPINA Study.

B. DEFINITIONS

For purposes of this agreement,

"Data" refers to all study data, including laboratory, examination, and questionnaire results, geographical information, or primary signal data (e.g., spirometry), and associated records either obtained directly from ESPINA participants or obtained from authorized third parties, including those arising from ESPINA ancillary studies.

"Resultant Data" refers to data derived in whole or in part by Recipient from Data and/or Materials provided under this ADD.

"ESPINA Study Investigator" is a research investigator who works with ESPINA either as an employee of UCSD or through a current and active contract or consulting agreement with UCSD.

"Research Project" refers to the project described in the attached research application.

"Recipient" refers to the institution or other entity receiving access to ESPINA Data requested for the Research Project identified in section 3 below as described in the attached research application.

"Principal Investigator (PI)" refers to the Research Project director for the Recipient.

TERMS AND CONDITIONS

It is mutually agreed as follows:

1. Data. ESPINA agrees to provide Recipient with Data described as follows (provide a copy of the variables requested in the **Manuscript Proposal and Dataset Request Form**):

The ESPINA study will provide Recipient with the name and contact information of Study Investigators and all other investigator(s) who generated such Data upon request.

2. Research Project.

2.1 These Data will be used by Recipient's PI solely in connection with the Research Project, as named and described in the attached research application (insert Research Project name below):

2.2 This ADD covers only the Research Project cited in section 2.1 of this ADD. Recipient must submit a separate ADD for each Research Project for which Data are requested.

3. Non-transferability.

This ADD is not transferable.

3.1 Recipient and Recipient's PI agree that substantive changes made to the Research Project, and/or appointment by Recipient of another Principal Investigator and/or transfer of Recipient's PI to another institution or other entity to complete the Research Project, require execution of a separate ADD. Recipient may not distribute Data to any other individual or entity, regardless of the intended use of such Data. However, nothing in this section precludes Recipient from publishing results of the Research Project through the usual channels of scientific publication.

4. Conduct of Research Project. Recipient's PI is responsible for the conduct of the Research Project and shall be responsible for assuring that any co-investigator(s) comply with the terms of this ADD.

5. Publication. Prompt publication of the results of the Research Project is encouraged. ESPINA requests that the Recipient's PI provide to the authorized representative the ESPINA Study, a copy of any abstract fifteen (15) days in advance of submission for publication and any manuscript or other disclosure document thirty (30) days in advance of submission for publication, to permit review and comment and ensure compliance with the confidentiality requirements of this ADD.

6. Acknowledgments. Recipient and Recipient's PI agree to acknowledge the contribution of ESPINA staff in any oral and written presentations, disclosures, and publications resulting from all analyses of Data.

6.1. Collaborations. If a manuscript resulting from the Research Project has Study Investigators as co-authors, then the manuscript will be reviewed by ESPINA.

6.1.a. If the manuscript is approved by ESPINA, the Recipient and Recipient's PI agree to include the following language in an acknowledgment.

"The Secondary Occupational Pesticide Exposure among Children and Adolescents (ESPINA) study was supported by the National Institute of Environmental Health Sciences (NIEHS) of the National

Institutes of Health under Awards R01ES025792, 1R01ES030378, R21ES026084 and the National Institute of Occupational Safety and Health (NIOSH) under Award 1R36OH009402. This manuscript has been reviewed by ESPINA for scientific content and consistency of data interpretation with previous ESPINA publications." The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

6.1.b. If the manuscript is not approved by ESPINA and the Recipient and Recipient's PI wish to proceed to publish without inclusion of Study Investigators as co-authors, the Recipient and Recipient's PI agree to include the following language in an acknowledgment.

"The Secondary Occupational Pesticide Exposure among Children and Adolescents (ESPINA) study was supported by the National Institute of Environmental Health Sciences (NIEHS) of the National Institutes of Health under Awards R01ES025792, R01ES030378, R21ES026084 and the National Institute of Occupational Safety and Health (NIOSH) under Award 1R36OH009402. This manuscript was not approved by the ESPINA study. The opinions and conclusions contained in this publication are solely those of the authors and are not endorsed by ESPINA or the NIEHS and should not be assumed to reflect the opinions or conclusions of either."

6.1.c. If the Research Project does not involve collaboration with Study Investigators, then the Recipient and Recipient's PI agree to include the following language in an acknowledgment.

"The Secondary Occupational Pesticide Exposure among Children and Adolescents (ESPINA) study was supported by the National Institute of Environmental Health Sciences (NIEHS) of the National Institutes of Health under Awards R01ES025792, 1R01ES030378, R21ES026084 and the National Institute of Occupational Safety and Health (NIOSH) under Award 1R36OH009402. This manuscript was not approved by the ESPINA study. This manuscript was not prepared in collaboration with investigators of ESPINA. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health or the ESPINA Study.

6.2. Ancillary Study Investigator Acknowledgments. If Data include data provided to ESPINA by ancillary study investigators, Recipient and Recipient's PI also agree to acknowledge their contribution in all oral and written presentations, disclosures, and publications resulting from all analyses of such Data.

7. Non-Identification. Recipient and Recipient's PI agree that Data will not be used, either alone or in conjunction with any other information, in any effort to determine the individual identities of any of the participants from whom Data were obtained or derived.

8. Compliance with Participants' Informed Consent. Recipient and Recipient's PI agree that Data, their progeny, and derivatives thereof will not be used for any purpose contrary to a participant's applicable signed informed consent document(s). Recipient and Recipient's PI agree to consult with Study Investigators and ascertain, specifically and in detail, the terms and conditions of applicable ESPINA informed consent documents.

9. No Distribution. Recipient and Recipient's PI agree to retain control over Data and their progeny, and derivatives thereof. Recipient and Recipient's PI further agree not to transfer Data and their progeny, and derivatives thereof, with or without charge, to any other entity or individual.

10. Resultant Data to be Provided to ESPINA. New and unique data generated from the existing ESPINA data is considered Resultant Data. Recipient and Recipient's PI will provide ESPINA investigators all Resultant Data in the electronic format specified by ESPINA. Recipient and Recipient's PI agree that ESPINA may distribute all such Resultant Data to all institutions requesting access for their identified

qualified scientific investigators to such Resultant Data and that submit to ESPINA a signed ADD comparable to this ADD. Recipient and Recipient's PI agree to provide ESPINA with a report every twelve (12) months during the term of this ADD. The report shall include a description of the activities performed and Resultant Data obtained during the twelve (12) months before the reporting date.

11. Non-Endorsement, Indemnification. Recipient and Recipient's PI agree not to claim, infer, or imply UCSD endorsement of the Research Project, the entity, or personnel conducting the Research Project.

Recipient and Recipient's PI agree to hold harmless UCSD, Fundacion CIMAS del Ecuador, the ESPINA study, and all investigator(s) who generated data, and the agents and employees of each of them, for all liabilities, demands, damages, expenses, and losses arising out of Recipient's use for any purpose.

Except where prohibited by law, Recipient agrees to defend and indemnify UCSD, Fundacion CIMAS del Ecuador, the ESPINA study, and all investigator(s) who generated data, and the agents and employees of each of them, for all liabilities, demands, damages, expenses, and losses arising out of Recipient's use for any purpose.

12. Accuracy of Data. Recipient agrees that the UCSD and ESPINA are not responsible for the accuracy of Data provided.

13. Recipient's Compliance with Recipient IRB's Requirements. Recipient certifies that the conditions for use of the Data in conjunction with the Research Project have been reviewed by the Recipient's Institutional Review Board (IRB) or similar human subjects oversight body in accordance with Department of Health and Human Services regulations at 45 CFR Part 46. Recipient agrees to comply fully with all such conditions and with the participants' informed consent documents, and any additional conditions that may be imposed by the ESPINA IRB(s). Recipient agrees to report promptly to ESPINA any unanticipated problems or proposed changes in the Research Project.

Recipient also agrees to report to Recipient's IRB any unanticipated problems or changes in the Research Project that involve additional risks to participants or others. Recipient remains subject to applicable state and local laws and regulations and institutional policies that provide additional protections for human subjects.

14. Recipient's Responsibility to follow Data Security Best Practices. Recipient is aware of computer and data security best practices and will follow them for receipt, storage and use of Data and Resultant Data. An example of best practice guidelines can be found in http://www.ncbi.nlm.nih.gov/projects/gap/pdf/dbgap_2b_security_procedures.pdf.

15. Amendments. Amendments to this ADD must be made in writing and signed by authorized representatives of all parties.

16. Termination. This ADD shall terminate at the earliest of: the completion of the Research Project; five (5) years after the effective date of this ADD; abandonment of the Research Project; or violation by Recipient of any provisions of this ADD not remedied within 30 days after the date of written notice by ESPINA of such violation. Upon termination of this ADD: Recipient agrees to consult with ESPINA regarding the disposition of all remaining Data.

17. Disqualification, Enforcement. Failure to comply with any of the terms of this ADD may result in disqualification of Recipient from receiving additional Data. UCSD and/or ESPINA may have the right to institute and prosecute appropriate proceedings at law or in equity against the Recipient for violating or threatening to violate the confidentiality requirements of this ADD, the limitations on the use of the Data provided, or both. Proceedings may be initiated against the violating party, or legal representatives, and assigns, for a restraining injunction, compensatory and punitive damages,

mandamus, and/or any other proceeding at law or in equity, including obtaining the proceeds from any intellectual property or other rights that are derived in whole or in part from the breach of the confidentiality requirements or use limitations of this agreement. In addition, Recipient and Recipient's PI acknowledge and agree that a breach or threatened breach of the confidentiality requirements or use limitations of this ADD may subject Recipient and Recipient's PI to legal action on the part of ESPINA participants, their families, or both.

18. Representations. Recipient and Recipient's PI expressly certify that the contents of any statements made or reflected in this document are truthful and accurate.

19. Prior Distribution Agreements. By execution of this ADD, Recipient certifies its good faith belief that it follows the terms and conditions of all its existing ADDs with ESPINA and/or UCSD.

Required Signatures begin on the next page

RECIPIENT'S PRINCIPAL INVESTIGATOR (Applicant) AND RECIPIENT'S
AUTHORIZED REPRESENTATIVE:

Name and Title of Recipient's Principal Investigator (Applicant)

Mail Address of Recipient's Principal Investigator (Applicant)

Email Address of Recipient's Principal Investigator (Applicant)

Signature of Recipient's Principal Investigator and date

Name of Recipient Corporation or Institution

ESPINA study authorization

Name and Title of ESPINA study Authorized Representative

Signature and Date of ESPINA study Representative

This Distribution Agreement is entered into effect as of _____(date MM/DD/YY)