

APPENDIX 6.
Institutional Review Board Approval

David Gimeno Ruiz de Porras
UT-H - SPH - San Antonio Regional Campus

NOTICE OF CONTINUING REVIEW APPROVAL

October 18, 2018

HSC-SPH-16-0803 - *Second Working Conditions and Health Survey in Central America (ECCTS-II) & Working Conditions and Health in Central America*

PI: David Gimeno Ruiz de Porras

PROVISOS: Unless otherwise noted, this approval relates to the research to be conducted under the above referenced title and/or to any associated materials considered at this meeting, e.g. study documents, informed consents, etc.

APPROVED: By Expedited Review and Approval

REVIEW DATE: 10/17/2018

APPROVAL DATE: 10/17/2018

CHAIRPERSON: Rebecca Lunstroth, JD



Upon review, the CPHS finds that this research is being conducted in accord with its guidelines and with the methods agreed upon by the principal investigator (PI) and approved by the Committee.

PLEASE NOTE: Due to revisions to the common rule that went into effect July 19, 2018, this study that was approved under expedited approval no longer needs to submit for continuing review. Changes to the study, adverse events, protocol deviations, personnel changes, and all other types of reporting must still be submitted to CPHS for review and approval. When this study is complete, the PI must submit a study closure report to CPHS

CHANGES: The PI must receive approval from the CPHS before initiating any changes, including those required by the sponsor, which would affect human subjects, e.g. changes in methods or procedures, numbers or kinds of human subjects, or revisions to the informed consent document or procedures. The addition of coinvestigators must also receive approval from the CPHS. **ALL PROTOCOL REVISIONS MUST BE SUBMITTED TO THE SPONSOR OF THE RESEARCH.**

UNANTICIPATED RISK OR HARM, OR ADVERSE DRUG REACTIONS: The PI will immediately inform the CPHS of any unanticipated problems involving risks to subjects or others, of any serious harm to subjects, and of any adverse drug reactions.

RECORDS: The PI will maintain adequate records, including signed consent documents if required, in a manner which ensures subject confidentiality.