



EAST CAROLINA UNIVERSITY

University & Medical Center Institutional Review Board Office
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TO: Ryan J. Cobey, Graduate Student, ECU, Department of Geography

FROM: UMCIRB *RJB*

DATE: May 10, 2011

RE: Expedited Category Research Study

TITLE: "Investigation into Public Opinion of the Ecuadorian Citizenship Regarding el Buen Vivir, an Ecuadorian Political Initiative of Alternative Social and Economic Development"

UMCIRB #11-0291

This research study has undergone review and approval using expedited review on **05/09/2011**. This research study is eligible for review under expedited category numbers six (6) and seven (7) which include collection of data from voice, video, digital, or image recordings made for research purposes and research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior), or research employing survey, interview, oral history, focus groups, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: some research in this category may be exempt from the HHS regulations for the protection of human subjects 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt. The Chairperson (or designee) deemed this **unfunded** study **no more than minimal risk** requiring a continuing review in **12 months**. Changes to this approved research may not be initiated without UMCIRB review except when necessary to eliminate an apparent immediate hazard to the participant. All unanticipated problems involving risks to participants and others must be promptly reported to the UMCIRB. The investigator must submit a continuing review/closure application to the UMCIRB prior to the date of study expiration. The investigator must adhere to all reporting requirements for this study.

The above referenced research study has been given approval for the period of **05/09/2011** to **05/08/2012**. The approval includes the following items:

- Internal Processing Form (UMCIRB receipt date 04/28/2011)
- Informed Consent – English version (version date 04/27/2011)
- Informed Consent – Spanish version (no version date)
- Interview Schedule – Spanish and English version
- Survey – Spanish and English version

The Chairperson (or designee) does not have a potential for conflict of interest on this study.

The UMCIRB applies 45 CFR 46, Subparts A-D, to all research reviewed by the UMCIRB regardless of the funding source. 21 CFR 50 and 21 CFR 56 are applied to all research studies under the Food and Drug Administration regulation. The UMCIRB follows applicable International Conference on Harmonisation Good Clinical Practice guidelines.

ACUERDO DE CONSENTIMIENTO

INTRODUCCIÓN

Este documento puede contener palabras que ud. no entiende. Usted debe preguntar a la investigadora a explicar cualquier palabras o información que no entiende.

Usted ha sido invitado a participar en un estudio llevado a cabo por Ryan Cobey, un alumno de East Carolina University en Greenville, Carolina del Norte, E.E.U.U. Le meta del estudio es mejor entender la policia del *Buen Vivir* y la percepción pública de los ciudadanos en Ecuador. La investigación explora los percepciones de la policia *Buen Vivir* de acuerdo con ciudadanos para aprender el nivel de comprensión así como el nivel de acuerdo de los ciudadanos que son afectados directamente por los policias. Los resultados del estudio nos ayudarán comprender mejor las policias y la situación política en Ecuador.

El estudio consiste de entrevistas con ciudadanos para aprender de sus experiencias y opiniones sobre los cambios políticos en Ecuador desde el nuevo constitucion en 2008 que presentó y explicó la nueva policia que se llama el *Buen Vivir*. Se ha pedido de ud. proveer una entrevista que durará un hora, mas o menos. La información que ud. provee será estrictamente privado y usado sólo por este propósito. Su nombre no será vinculado a la información que ud. provee.

La entrevistadora pedirá su permiso a grabar la entrevista para permitir documentar correctamente sus repuestas y para consultar más tarde. La grabación no se usará para fines fuera de este estudio.

ACUERDO DE CONSENTIMIENTO

Yo he sido invitado a participar en una investigación llevado a cabo por Ryan Cobey. Yo entiendo el propósito de la investigación y entiendo que los riesgos a mi persona son mínimos. Yo entiendo que cualquier información que yo doy se mantendrá privado y confidencial.

Yo entiendo que mi participación en este estudio es voluntario y puedo terminar cuando yo quiero. Yo puedo elegir no responder a ciertas preguntas sin dejar de participar. Si yo en cualquier momento tengo preguntas sobre este estudio, el investigador estará disponible para correo electronico: cobeyr05@students.ecu.edu

- 3 He leído y/o entiendo toda de la información arriba, hice preguntas y he recibido respuestas satisfactorias en las áreas que no entendí.
- 3 Acepto participar voluntariamente en esta investigación.
- 3 No quiero participar en esta investigación.

PERSONA ADMINISTRANDO EL ACUERDO: Yo he llevado a cabo el proceso de acuerdo y he repasado oralmente el contenido de este documento de acuerdo. Yo pienso que el participante entiende la investigación.

Persona Obteniendo Acuerdo (**LETRAS**) Firma Fecha

Investigador(a) Principal (**LETRAS**) Firma Fecha

UMCIRB
APPROVED

FROM
TO

05-09-11
05-08-12

INFORMED CONSENT DOCUMENT

INTRODUCTION

This document may contain information that you do not understand. In this case, you should ask the principle investigator to explain any words or pieces of information that you do not understand or on which you need clarification

You have been invited to participate in a study carried out by Ryan Cobey, a student from East Carolina University in Greenville, NC, United States. The purpose of this study is to better understand the Ecuadorian policy of *Buen Vivir* in regard to public perceptions from citizens in Ecuador. This investigation explores citizens' perceptions of new government policies under *Buen Vivir* to better understand the level of comprehension and satisfaction from the citizenship which is directly affected by these new policy changes. The results of this study will help to gain a greater understanding of changes to political policies in Ecuador.

The study consists of interviews with Ecuadorian citizens in order to learn about recent political changes in Ecuador since the creation of a new constitution in 2008 from their experiences and perceptions. It is requested that you provide enough time to complete the interview process, which should take more or less 1 hour. The information that you provide will be strictly private and used only for this study. Your name will *not* be presented with the information you provide.

Your permission is requested to audio record the interview in order to correctly document and analyze your responses at a later date. The recording will *not* be used after the completion of this study.

AGREEMENT FOR CONSENT

I have been invited to participate in an investigation carried out by Ryan Cobey. I understand the above information and I understand that the risks to my person are minimal. I understand that any information that I provide will be maintained private and confidential.

I understand that my participation in this study is voluntary and I can choose to leave or quit the study whenever I want. I can also choose not to respond to certain questions without completely stopping the interview. If at any moment I have questions about the study, the investigator will be able to be reached at the following email: cobeyr105@students.ecu.edu

- 3 I have read and understand all of the above information. Any questions I had have been answered to my satisfaction in any area that I did not understand.
- 3 I will participate voluntarily in this study
- 3 I do not wish to participate in this study

ADMINISTRATOR AGREEMENT: I have carried out the process of agreement and have reviewed orally the content of this document. I believe that to the best of my knowledge the participant understands this investigation.

Individual Giving Consent (Printed Name) _____ Signature _____ Date _____

Principal Investigator (Printed Name) _____ Signature _____ Date _____

**UMCIRB
APPROVED**

FROM 05-09-11
TO 05-08-12

*****IMPORTANT INFORMATION*****

Continuing and Final Review Obligations

As Principal Investigator, you are required to submit a continuing or final review form to the Office for Human Research Integrity for IRB review. This is a federal requirement to continue or close your research study before the date of expiration as noted on the attached approval letter. This information is required to summarize the research activities since it was last approved. The regulations do not permit any research activity outside of the IRB approval period. Additionally, the regulations do not permit the UMCIRB to provide a retrospective approval during a period of lapse.

You must submit this form even if there has been no activity, no participants enrolled or you do not wish to continue the activity any longer. Research studies that are allowed to be expired will be reported to the Vice Chancellor for Research and Graduate Studies, along with relevant other administration within the institution. The continuing or final review form is located on our website at <http://www.ecu.edu/rgs/irb/> along with our meeting submission deadlines. Please contact the UMCIRB office at 252-744-2914 if you have any questions regarding your role or requirements with continuing review.

Required Approval for Any Changes to IRB-Approved Research

As Principal Investigator, you are required, prior to making any changes in your research study must have those changes reviewed and approved by the IRB. The only exception is when those changes are to eliminate an immediate apparent hazard to the participant. In the case when changes must be immediately undertaken to prevent a hazard to the participant and there is no opportunity to obtain prior IRB approval, the IRB must be informed of the changes as soon as possible via a protocol deviation form.

Reporting Unanticipated Problems to the IRB that Affect Participants or Others

As Principal Investigator, you are required to report to the IRB all unanticipated problems that have occurred in your research within the time frame specified in the UMCIRB rule for reporting Unanticipated Problems Involving Risks to Participants or Others.