

Appendix 1.1 Ethics approval letters

London School of Hygiene & Tropical Medicine

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Observational / Interventions Research Ethics Committee

Ms Georgina Miguel Esponda
LSHTM

18 May 2017

Dear Georgina

Study Title: Assessment of the implementation determinants and their influence on outcomes of a programme for common mental disorders in primary health clinics in Chiapas, Mexico

LSHTM Ethics Ref: 11955

Thank you for responding to the Observational Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Conditions of the favourable opinion

Approval is dependent on local ethical approval having been received, where relevant.

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document Type	File Name	Date	Version
Investigator CV	CV.Georgina_Miguel_2017	26/02/2017	1
Protocol / Proposal	Appendix 1_Focus group guide_determinants	26/02/2017	1
Protocol / Proposal	Appendix 2_Observation guide	26/02/2017	1
Protocol / Proposal	Appendix 3_Guide indepth interviews_MSs and supervisors	26/02/2017	1
Protocol / Proposal	Appendix 4_Guide indepth interviews_patients	26/02/2017	1
Protocol / Proposal	Appendix 5_ENACT Scale	26/02/2017	1
Protocol / Proposal	Appendix 6_Satisfaction survey	26/02/2017	1
Protocol / Proposal	Appendix 7_Guide semi-structured interviews_MSs and supervisors	26/02/2017	1
Information Sheet	Annex 8_Information sheet	26/02/2017	1
Information Sheet	Annex 9_Consent form	26/02/2017	1
Local Approval	thumbnail_Georgina Miguel Esponda028	27/03/2017	1
Protocol / Proposal	MHIS_authorisationletter	07/05/2017	1
Protocol /	Protocol_Implementation determinants and outcomes of a mental health	07/05/2017	2

Proposal	programme_Version2	
Covering Letter	Cover_letter_Ethicsref11955	09/05/2017 2
Information Sheet	Annex 8_Information sheet_version2	09/05/2017 2

After ethical review

The Chief Investigator (CI) or delegate is responsible for informing the ethics committee of any subsequent changes to the application. These must be submitted to the Committee for review using an Amendment form. Amendments must not be initiated before receipt of written favourable opinion from the committee.

The CI or delegate is also required to notify the ethics committee of any protocol violations and/or Suspected Unexpected Serious Adverse Reactions (SUSARs) which occur during the project by submitting a Serious Adverse Event form.

At the end of the study, the CI or delegate must notify the committee using an End of Study form.

All aforementioned forms are available on the ethics online applications website and can only be submitted to the committee via the website at: <http://leo.lshtm.ac.uk>

Additional information is available at: www.lshtm.ac.uk/ethics

Yours sincerely,



Professor John DH Porter
Chair

ethics@lshtm.ac.uk
<http://www.lshtm.ac.uk/ethics/>

Improving health worldwide

**SECRETARÍA DE SALUD
INSTITUTO DE SALUD
DIRECCIÓN DE ATENCIÓN MÉDICA
SUBDIRECCIÓN DE EDUCACIÓN Y ENSEÑANZA EN SALUD.**

Oficio No.: **5033/1800**
Asunto: Evaluación bioética..

Tuxtla Gutiérrez, Chiapas a 27 de marzo de 2017

Georgina Miguel Esponda.

Departamento de Salud Mental
Facultad de Epidemiología y Salud Poblacional
London School of Hygiene and Tropical Medicine
Presente.

Se ha leído con mucha atención el protocolo "Evaluación de los determinantes de la implementación y su influencia en los resultados de un programa para trastornos mentales comunes en clínicas de salud primaria en Chiapas, México"

Explora las condiciones en las que se da atención a la salud mental en los hospitales de atención primaria en el estado.

Los problemas de salud mental en las sociedades actuales son graves tanto en el número, como en las consecuencias de los que la padecen y que desafortunadamente a veces son no atendidos correctamente.

En este trabajo se va a evaluar a los profesionales de la salud que proporcionan la atención, así como a los usuarios, es decir los pacientes atendidos y conocer de estos últimos el grado de satisfacción.

Es un trabajo complejo en el que la realidad puede sesgarse por problemas de confianza y comunicación.

En el escrito identifican los posibles riesgos que implica el trabajo sobre todo en la confidencialidad de la información que recabarán, también mencionan las medidas que se tomarán para evitar su dispersión.

No se detecta ningún conflicto bioético, por lo que se **APRUEBA** el proyecto para su ejecución.

Les pedimos que nos informen de cualquier contingencia que se presente durante el desarrollo del trabajo, así como un pequeño informe final.

Atentamente

Dr. Luis Ángel Terán Ortiz.

Comisión de Bioética del
Estado de Chiapas.

Ccp. Minutario.

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Observational / Interventions Research Ethics Committee

Ms. Georgina Miguel Esponda
LSHTM

20 February 2019

Dear Georgina,

Study Title: Assessment of the implementation determinants and their influence on outcomes of a programme for common mental disorders in primary health clinics in Chiapas, Mexico

LSHTM Ethics Ref: 11955 - 1

Thank you for your letter responding to the Observational Committee's request for further information on the above amendment to research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above amendment to research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Conditions of the favourable opinion

Approval is dependent on local ethical approval for the amendment having been received, where relevant.

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document Type	File Name	Date	Version
Other	Appendix 1_consentform_providers	01/03/2017	2
Other	Appendix 2_consentform_users	01/03/2017	2
Other	Protocol_Implementation determinants and outcomes of a mental health programme_161118	16/11/2018	3
Covering Letter	cover_letter_11955_1	13/01/2019	1
Local Approval	SSP_CHIAPAS_5003_0561	07/02/2019	1
Covering Letter	cover_letter_11955_2	07/02/2019	2

After ethical review

The Chief Investigator (CI) or delegate is responsible for informing the ethics committee of any subsequent changes to the application. These must be submitted to the Committee for review using an Amendment form. Amendments must not be initiated before receipt of written favourable opinion from the committee.

The CI or delegate is also required to notify the ethics committee of any protocol violations and/or Suspected Unexpected Serious Adverse Reactions (SUSARs) which occur during the project by submitting a Serious Adverse Event form.

An annual report should be submitted to the committee using an Annual Report form on the anniversary of the approval of the study during the lifetime of the study.

At the end of the study, the CI or delegate must notify the committee using an End of Study form.

All aforementioned forms are available on the ethics online applications website and can only be submitted to the committee via the website at: <http://leo.lshtm.ac.uk>

Additional information is available at: www.lshtm.ac.uk/ethics

Yours sincerely,



Professor John DH Porter
Chair

ethics@lshtm.ac.uk
<http://www.lshtm.ac.uk/ethics/>

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INSTITUTO DE SALUD
DIRECCIÓN DE ATENCIÓN MÉDICA
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DEPARTAMENTO DE ENLACE CIENTÍFICO Y ACADÉMICO

Oficio No.: **5003/0561**
Asunto: Extensión de Aprobación
Bioética de Investigación.

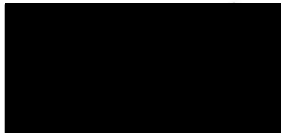
Tuxtla Gutiérrez, Chiapas a 7 de febrero de 2019.

Dr. Georgina Miguel Esponda
Departamento de Salud Poblacional
London School of Hygiene and Tropical Medicine.
Reino Unido.

En atención a su solicitud de extensión del visto bueno Bioético a su protocolo "Evaluación de los determinantes de la implementación y su influencia en los resultados de un programa para trastornos mentales comunes en las clínicas de salud primaria de Chiapas, México", los cambios consisten en un tiempo extra de 12 meses para completar el análisis de los datos recolectados y la incorporación de dos investigadores.

Nos damos por enterados, esto no cambia el status de la opinión, continuando en **ACEPTADO**.

Atentamente.



Dr. Luis Ángel Terán Ortiz.
Secretario Técnico de la Comisión de Bioética.

Ccp.- Minutario.