

26 November 2015

Prof Umberto D'Alessandro
Unit Director/DCE Theme Leader
MRC Unit, The Gambia
Fajara

Dear Prof D'Alessandro

SCC 1447v2, Reactive household-based self-administered treatment against residual malaria transmission: site preparation and baseline survey

Thank you for submitting your proposal dated 09 October 2015 for consideration by The Gambia Government/MRC Joint Ethics Committee at its meeting held on 30 October 2015.

The Committee has carefully considered this proposal and is pleased to provide its approval.

With best wishes

Yours sincerely



Mr Malamin Sonko
Chairman, Gambia Government/MRC Joint Ethics Committee

Documents submitted for review:-

- Response letter – 10 October 2015
- SCC Application Form, version 2.0 – 09 October 2015
- Informed Consent Form (adult/census), version 1.0 – 15 September 2015
- Informed Consent Form (adult/survey), version 1.0 – 18 September 2015
- Informed Consent Form (child/survey), version 1.0 – 18 September 2015

The Gambia Government/MRC Joint Ethics Committee:

Mr Malamin Sonko, Chairman
Professor Ousman Nyan, Scientific Advisor
Ms Naffie Jobe, Secretary
Dr Roddie Cole
Dr Ahmadou Lamin Samateh
Mrs Tulai Jawara Ceesay

Prof. Umberto D'Alessandro
Dr Momodou L. Waggeh
Dr Kalifa Bojang
Dr Ramatoulie Njie
Dr Jane Achan
Dr Siga Fatima Jagne

19 October 2015

Dr Koen Peeters
Institute of Tropical Medicine
Antwerp, Belgium

Dear Peeters

SCC 1438v2, The impact of socio-cultural and health system factors on asymptomatic malaria carriers' adherence to antimalarial treatment in the Gambia

Thank you for submitting your proposal dated 15 September 2015 for consideration by The Gambia Government/MRC Joint Ethics Committee at its meeting held on 02 October 2015.

Our committee has carefully considered your request for this project and is pleased to approve your proposed study.

With best wishes

Yours sincerely



Mr Malamin Sonko
Chairman, Gambia Government/MRC Joint Ethics Committee

Documents submitted for review:-

- SCC Application Form, version 2.0 – 15 September 2015
- Response letter – 15 September 2015
- Cover letter
- Preliminary topic guide
- Guidance Note for Researchers and Evaluators of Social Sciences and Humanities Research – 2010
- Informed Consent Document (health workers), version 1.0 – 15 September 2015
- Informed Consent Document (general), version 1.0 – 15 September 2015
- CVs: Susan Dierickx, Melanie Bannister-Tyrrell, Koen Peeters Grietens; Julie Balen; Joan Muela Ribera; Fatou Jaiteh
- AAA Statement on Ethnography and Institutional Review Boards – 4 June 2004
- Code of Ethics of the American Anthropological Association, Approved June 1998
- The European Code of Conduct for Research Integrity

The Gambia Government/MRC Joint Ethics Committee:

Mr Malamin Sonko, Chairman
Professor Ousman Nyan, Scientific Advisor
Ms Naffie Jobe, Secretary
Dr Roddie Cole
Dr Ahmadou Lamin Samateh
Mrs Tulai Jawara Ceesay

Prof. Umberto D'Alessandro
Dr Momodou L. Waggeh
Dr Kalifa Bojang
Dr Ramatoulie Njie
Dr Jane Achan
Dr Siga Fatima Jagne

13 June 2016

Dr Julie Balen
School of Health and Related Research (SchHARR)
The University of Sheffield

Dear Dr Balen

SCC 1480v2, Health systems research for developing, assessing, monitoring and evaluating implementation strategies for, and preliminary impact of RHOST

Thank you for submitting your proposal dated 12 May 2016 for consideration by The Gambia Government/MRC Joint Ethics Committee at its meeting held on 27 May 2016.

The Ethics Committee has reviewed your research ethics application and is pleased to approve your proposed study.

Members also suggested that the Regional Health Team be included in the study as collaborator.

With best wishes

Yours sincerely



Mr Malamin Sonko
Chairman, Gambia Government/MRC Joint Ethics Committee

Documents submitted for review:-

- SCC approval letter – 17 May 2016
- SCC application form, version 2.0 – 12 May 2016
- Code of Ethics of the AAA, Approved June 1998
- The AAA statement on ethnography and institutional review boards adopted by AAA
- Executive Board 4 June 2004
- Documentation of consent by researcher, Version 1.0 – 24 August 2015
- Consent for Research Participation, Version 1.0 – 24 August 2015
- Consent for Research Participation
- CVs: Julie Balen; Nicola Love; Deirdre Wholly

The Gambia Government/MRC Joint Ethics Committee:

*Mr Malamin Sonko, Chairman
Professor Ousman Nyan, Scientific Advisor
Ms Naffie Jobe, Secretary
Dr Roddie Cole
Dr Ahmadou Lamin Samateh
Mrs Tulai Jawara-Ceesay*

*Prof. Umberto D'Alessandro
Dr Ramatoulie Njie
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Dr Momodou L. Waggeh
Dr Siga Fatima Jagne*



REPUBLIC OF THE GAMBIA

MINISTRY OF HEALTH & SOCIAL WELFARE
THE QUADRANGLE
BANJUL

Tel: 4227300/4227301

Fax: 4229325

Ref: DHS/AD/2016/01

29th February, 2016

Professor Umberto D'Alessandro MD PhD

Unit Director

MRC Unit, The Gambia

Fajara

**RE: REQUEST TO CONDUCT HEALTH SYSTEMS RESEARCH
WITHIN THE RHOST STUDY**

I am please to inform you that approval has been granted for you to conduct Health System Research and Social Field Work as part of the Framework of collaborative project entitled "**Reactive Household-based Self-administered Treatment against Residual Malaria Transmission: a cluster randomized trial**" (RHOST).

By a copy of this letter, the Regional Health Director North Bank Region is hereby informed.

Please be assured of our continuous support and cooperation.

Yours sincerely,

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Dr. Samba Ceesay
Acting Director of Health Services

Cc: Permanent Secretary – MoH&SW
Regional Health Director – North Bank Region

Files



UNIVERSITY of WASHINGTON

HUMAN SUBJECTS DIVISION

May 13, 2016

PI: Deidre Wholly, Graduate Student
Department of Global Health

CC: Joseph Babigumira, PhD; Assistant Professor
Department of Global Health

RE: HSD Study #51982, "Collaboration Between Health Facilities and the Village Health Services in a Sub-Region of The Gambia"

Dear Ms. Wholly:

The University of Washington Human Subjects Division (HSD) has determined that your research qualifies for exempt status in accordance with the federal regulations under 45 CFR 46.101. Details of this determination are as follows:

Exempt category determination: Category 2.

Although research that qualifies for exempt status is not governed by federal requirements for research involving human subjects, investigators still have a responsibility to protect the rights and welfare of their subjects, and are expected to conduct their research in accordance with the ethical principles of *Justice, Beneficence* and *Respect for Persons*, as described in the Belmont Report, as well as with state and local institutional policy.

Determination Period: This exempt determination is valid for the life of the study, as long as the nature of the research activity remains the same. If there is any substantive change to the activity that has determined to be exempt, one that alters the overall design, procedures, or risk/benefit ratio to subjects, the exempt determination will no longer be valid.

Revisions: Only modifications that are deemed "minor" are allowable, in other words, modifications that do not change the nature of the research and therefore do not affect the validity of the exempt determination. **Please refer to the Guidance document for more information about what are considered minor changes.** If changes that are considered to be "substantive" occur to the research, that is, changes that alter the nature of the research and therefore affect the validity of the exempt determination, a new *Exempt Status Request* must be submitted to HSD for review and determination *prior to implementation*.

Problems: If issues should arise during the conduct of the research, such as unanticipated problems, adverse events or any problem that may increase the risk to the human subjects and change the category of review, notify HSD promptly. Any complaints from subjects pertaining to the risk and benefits of the research must be reported to HSD.

Please use the HSD study number listed above on any forms submitted which relate to this research, or on any correspondence with the HSD office.

Good luck in your research. If we can be of further assistance, please contact us at (206) 543-0098 or via email at hsdinfo@uw.edu. Thank you for your cooperation.

Sincerely,

Chase Nordengren, PhD
Administrator, IRB J / Subcommittee EJ
Human Subjects Division