

**Hawassa University
College of Medicine and Health Sciences
Institutional Review Board comments**

11) Title of proposal (Version 1): Assessment of household play space intervention to reduce infant <i>Compylobacter</i> infection in Ethiopia: A randomized controlled feasibility trial
Investigators: Sophie Budge, Alison Parker, Paul Hutchings
Contact address: Telephone: _____ Email: _____
Reviewer:
Type of submission: New
Comments: - Translate the questionnaire to local language
Decision: Approved with recommendation
Version 2:

NOTE TO THE INVESTIGATORS:

- 1) Revise the protocol as per the comments given.
- 2) Prepare a point-by-point response to the comments given in a separate paper.
- 3) Bring a copy of the revised protocol and the point-by-point response to obtain the ethical clearance.
- 4) If it is a case of resubmission, the revised protocol and the point-by-point response shall be brought for submission in double copies and protocol processing fees apply.



Ref. No: IRB/010/12

Date: 10/01/2019

Meeting No: 04/2012

Name of Researcher(s): Sophie Budge, Alison Parker, Paul Hutchings

Topic of Proposal: Assessment of household play space intervention to reduce infant Compylobacter infection in Ethiopia: A randomized controlled feasibility trial

Dear researcher(s),

The Institutional Review Board (IRB) at the College of Medicine and Health Sciences of Hawassa University has reviewed the aforementioned research protocol with special emphasis on the following points:

- | | | | | |
|--|-----|-------------------------------------|----|--------------------------|
| 1. Are all principles considered? | | | | |
| 1.1. Respect for persons: | Yes | <input checked="" type="checkbox"/> | No | <input type="checkbox"/> |
| 1.2. Beneficence: | Yes | <input checked="" type="checkbox"/> | No | <input type="checkbox"/> |
| 1.3. Justice: | Yes | <input checked="" type="checkbox"/> | No | <input type="checkbox"/> |
| 2. Are the objectives of the study ethically achievable? | Yes | <input checked="" type="checkbox"/> | No | <input type="checkbox"/> |
| 3. Are the proposed research methods ethically sound? | Yes | <input checked="" type="checkbox"/> | No | <input type="checkbox"/> |

Based on the aforementioned ethical assessment, the IRB has:

- | | | |
|---|-------------------------------------|---|
| A. Approved the proposal for implementation | <input checked="" type="checkbox"/> | -Approval period from Jan 10/ 2020 to Jun 9/ 2020 |
| B. Conditionally Approved | <input type="checkbox"/> | -Element Approved: Protocol Version No. 1 |
| C. Not Approved | <input type="checkbox"/> | -Follow up report expected in 3 months |

Obligation of the PI:

1. Should comply with the standard international and national scientific and ethical guidelines
2. All amendment and changes made in protocol and consent form needs IRB approval
3. The PI should report SAE within 3 days of the event
4. End of study, including manuscript should be reported to the IRB

Yours faithfully,

Dawit Jember
Institutional Review Board Chairperson.

