



Government of Nepal

Nepal Health Research Council (NHRC)



Ref. No.: 1056

16 December 2016

Dr. Ram Krishna Chandyo
Dr. Laxman Prasad Shrestha
Principal Investigator
Child Health Research Project, Institute of Medicine
Kathmandu, Nepal

Subject: Approval of research proposal entitled **Supplementation of Vitamin B12 in pregnancy and postpartum on growth and neuro development in early childhood: A Randomized, placebo Controlled Trial among Pregnant women in Bhaktapur, Nepal**

Dear Dr. Chandyo and Dr. Shrestha

It is my pleasure to inform you that the above-mentioned proposal submitted on **31 August, 2016 (Reg.no. 253/2016)** please use this Reg. No. during further correspondence) has been approved by NHRC Ethical Review Board on **07 December 2016**.

As per NHRC rules and regulations, the investigator has to strictly follow the protocol stipulated in the proposal. Any change in objective(s), problem statement, research question or hypothesis, methodology, implementation procedure, data management and budget that may be necessary in course of the implementation of the research proposal can only be made so and implemented after prior approval from this council. Thus, it is compulsory to submit the detail of such changes intended or desired with justification prior to actual change in the protocol before the expiration date of this approval. Expiration date of this study is **December 2019**.

If the researcher requires transfer of the bio samples to other countries, the investigator should apply to the NHRC for the permission. The researchers will not be allowed to ship any raw/crude human biomaterial outside the country; only extracted and amplified samples can be taken to labs outside of Nepal for further study, as per the protocol submitted and approved by the NHRC. The remaining samples of the lab should be destroyed as per standard operating procedure, the process documented, and the NHRC informed.

Further, the researchers are directed to strictly abide by the National Ethical Guidelines published by NHRC during the implementation of their research proposal and submit progress report and full or summary report upon completion.

As per your research proposal, the total research amount is **NRs. USD 500,000.00** and accordingly the processing fee amount to **NRs. 1,613,550.00**. It is acknowledged that the above-mentioned processing fee has been received at NHRC.

If you have any questions, please contact the Ethical Review M & E section of NHRC.

Thanking you,

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Dr. Khem Bahadur Karki
Member Secretary