

To: Cheryl Moyer

From:

Thad Polk

Cc:

Cheryl Moyer

Subject: Notice of Determination of “Not Regulated” Status for [HUM00093372]

SUBMISSION INFORMATION:

Title: Preventing Maternal and Neonatal Mortality in Rural Northern Ghana

Full Study Title (if applicable):

Study eResearch ID: [HUM00093372](https://eresearch.umich.edu/HUM00093372)

Date of this Notification from IRB: 9/15/2014

Date of IRB Not Regulated Determination: 9/15/2014

IRB NOT REGULATED STATUS:

Category Outcome Letter Text

Quality Assurance and Quality Improvement Activities - Other

Based on the information provided, the proposed study does not fit the definition of human subjects research requiring IRB approval (per 45 CFR 46, 21 CFR 56 and UM policy). Although the results of your project may be published, program evaluations, self-assessment of programs or business practices, and other quality improvement projects do not require IRB review because in these cases, it is the activities rather than humans subjects that are the objects of the study.



Thad Polk
Chair, IRB HSBS