Requirements for an Acknowledgment of Unregulated Research Activities (v8.28.2015)

Some foreign research regulations do not require ethical oversight of Minimal Risk research studies. In these cases, documentation from an appropriate regulatory official, indicating the research study does not require foreign ethics oversight, is required for Pitt IRB submission.

Who can act as the appropriate regulatory official will vary based upon location. For example, this may come from the Chairman of an IRB or Ethics Committee, a University Administrator or Government Official depending upon local research infrastructure.

Documentation indicating regulatory oversight is not required should be obtained in the form of an Acknowledgement of Unregulated Research Activities letter. The materials below provide information on what content is required in this type of letter.

The West Africa Ministry of Health	The memo must be provided on letterhead.
8/26/2015	The memo must be dated.
TO: University of Pittsburgh IRB	
FROM: Amina Jallow, MD Deputy Director of Health	The memo must be provided by an appropriate Regulatory Official
RE: <Title of project – this must match the title given in OSIRIS>	The memo must reference the title of the OSIRIS research protocol.
Dr. Hector Hernandez has consulted with the West Africa Ministry of Health regarding the above referenced research study he intends to implement in Banjul, Gambia.	
Dr. Hernandez intends to conduct a public health research study on childhood vaccination rates. The research activities are purely observational. Participation will not affect the clinical care of enrolled subjects. No distribution of medicine or clinical procedures will be completed as part of research activities.	The memo must indicate the Regulatory Official understands the topic of the research and research procedures.
The Federal Research regulations of Gambia do not require regulatory oversight of non-clinical research trials. Therefore, no regulatory oversight is required for this research study in Gambia.	The memo must include a statement that regulatory oversight of the research study is not required and provide an explanation of why.
Please contact me if you have questions or concerns.	
Sincerely, Dr Amina Jallow	The memo must be signed.
Dr. Amina Jallow Deputy Director of Health The West Africa Ministry of Health ajallow@tgmoh.org	