TERMS OF REFERENCE FOR AN INDEPENDENT REVIEW OF THE PROTOCOL FOR THE WHO MULTICENTRE STUDY FOR THE DEVELOPMENT OF GROWTH STANDARDS FROM FETAL LIFE TO CHILDHOOD DEVELOPED BY THE WORLD HEALTH ORGANIZATION (WHO) AND THE PROTOCOL FOR THE INTERGROWTH 21ST STUDY DEVELOPED BY UNIVERSITY OF OXFORD

These terms of reference have been developed to guide the conduct of a review of the above mentioned two protocols by a group of independent experts appointed by WHO (“the Expert Group” or “EG”).

The EG will consist of three internationally reputed experts selected by the World Health Organization. The three experts must be free of any conflict of interest. In particular, the experts should have no existing or past (over the last four years) relationship with either the World Health Organization, or Oxford University (whether through employment, consultancy, advisorship, contract or otherwise), nor any involvement in the above mentioned studies. Each prospective expert will be required to attest to the above in writing, and be required to complete the WHO Declaration of Interest, before his/her appointment can be confirmed. In addition, each expert will be required to enter into an appropriate confidentiality undertaking.

The EG will comprise:

1. One expert in obstetric ultrasound and fetal growth assessment
2. One expert in research ethics
3. One senior public health figure with expertise in reproductive health research

WHO will approach international professional associations with the request to provide it with expressions of interest from potentially qualified individuals.

THE TASK

The EG will be required to compare the above mentioned two protocols in a detailed manner, and (given that the protocol for the WHO protocol was prepared before the protocol for the Oxford University study) provide their opinion on the following questions:

1. Are there similarities between the two protocols that suggest that Oxford University used text/content/concepts/ideas of the WHO protocol when preparing the protocol for the Intergrowth 21st Study (due regard being given to material in the public domain at the time of development of the Oxford University protocol)?
2. Have parts of the text of the WHO protocol been copied in the Oxford University protocol and if so, to what extent (due regard being given to material in the public domain at the time of development of the Oxford University protocol)?
3. What is the experts’ assessment of the intellectual ownership of the research question in, and overall content of, each protocol?
4. Based on the first three questions, are the experts of the opinion that research misconduct (as defined by the UK Research Integrity Office - UKRIO) is likely to have occurred in the preparation of the Oxford University protocol?

1 See http://ukrio.org/publications/code-of-practice-for-research/3-0-standards-for-organisations-and-researchers/3-16-misconduct-in-research
The experts will provide a written report of their findings to WHO. Any dissenting views should be noted in the report.

**PROCESS**

1. WHO will provide the experts with a copy of both protocols. The experts will be required to research relevant material in the public domain themselves.

2. All three experts will review the two protocols and relevant material in the public domain independently. They will subsequently discuss their findings, address the above mentioned questions, and prepare their report, jointly. Except as provided in these Terms of Reference, the experts will agree on their method of work.

3. Consistent with the above mentioned confidentiality undertaking, the experts will keep their deliberations and findings, and the content of their report, in confidence.

4. The experts will be reimbursed by WHO for their reasonable expenses incurred in the conduct of this review.

5. WHO will provide Oxford University with a confidential copy of the report of the EG. Both the Bill and Melinda Gates Foundation and the experts of the WHO Fetal Growth Study will be allowed to review the report on WHO premises, subject to obligations of confidentiality.

6. If the report of the EG indicates that research misconduct is likely to have occurred, WHO will refer the matter to the General Medical Council in the United Kingdom. If on the other hand, the report of the EG indicates that research misconduct is unlikely to have occurred, the matter will end there.