Independent Expert 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.

Report from the reviewers

26 July 2016

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)?

There was agreement that the protocols were almost identical, with much of the background, including standards for measurements, being in the public domain, except for the use of fetal 3D-ultrasound and postnatal growth curves for preterm babies. There was also agreement that the selection criteria were identical to a high degree, and unlikely to have been independently drafted. It was acknowledged that research into fetal growth standards was important, and that the Intergrowth 21st Study group had secured significant grant funding, while funding was still in progress for the WHO Study group.

There was no acknowledgement of the WHO protocol, nor people involved in its creation and evolution, in the Intergrowth Protocol, nor in the publications of the Intergrowth 21st Study.

It was noted that two scientists from Oxford University developed the Intergrowth Protocol and obtained a grant from the Bill and Melinda Gates Foundation to conduct the Intergrowth 21st Study while participating in the WHO Study group. They did not inform WHO and the other members of the WHO Study group of this.

It was furthermore noted that one of the two Oxford University scientists was contracted by WHO to write the protocol for the WHO Study. It appeared that he was simultaneously working on the protocol for the Intergrowth 21st Study.

Finally, it was noted that the spouse of this latter scientist (a WHO employee from another department than the department which was developing the WHO Study) contributed to the Intergrowth 21st Study.

The reviewers agreed that the above persons clearly had a conflict of interest, which they omitted to disclose.
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)?

No formal assessment through plagiarism software was made. Both protocols include the rationale as continuing the WHO Multi Centre Growth Reference Study (MGRS) work. The overlap in the two protocols seems obvious and significant. Overall, the Oxford protocol reads as though it used the WHO protocol as a base and modified it. The protocols are arranged differently and some of the content is available in the public domain. Several phrases are exactly the same, several sentences are almost the same but sequencing of words is different. The order of items listed is identical in several chapters.

3. What is the experts’ assessment of the intellectual ownership of the research question in, and overall content of, each protocol?

The structure and contents of a large proportion of the two protocols are very similar. The intellectual ownership of the research question belongs to WHO since WHO experts promoted the main idea since mid 1990s.

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?

The reviewers reached consensus that research ethics misconduct occurred, based on the existence of undeclared Conflicts of Interest by several persons, involved in the Intergrowth Study, including the PI for the Intergrowth 21st Study, the above mentioned scientists and his spouse at WHO.