PRESIDENTIAL COMMISSION FOR THE STUDY OF BIOETHICAL ISSUES

October 30, 2013

Ms. Kate Harvey
Research Officer
Nuffield Council on Bioethics
28 Bedford Square
London WC1B3JS

Dear Ms. Harvey,

I am writing on behalf of Dr. Amy Gutmann, Chair, and the U.S. Presidential Commission for the Study of Bioethical Issues (Bioethics Commission) to respond to the Nuffield Council on Bioethics' open consultation on the ethical issues arising out of children's involvement in clinical research.

In March 2013, the Bioethics Commission published *Safeguarding Children: Pediatric Medical Countermeasure Research*, in which it conducted a thorough review of the ethical considerations of conducting clinical trials of medical countermeasures (MCMs) with children. (The Bioethics Commission considered the term MCM to encompass all U.S. Food and Drug Administration regulated products and interventions used in response to chemical, biological, radiological, and nuclear attacks.) The full report is available at http://bioethics.gov/node/833.

While the Bioethics Commission's work is relevant to many of the questions posed in the call for evidence, *Safeguarding Children* addresses **Question 9** extensively:

> **Are there any situations in which you think it would be acceptable for a child to be invited to participate in clinical research when there will not be *any* personal benefit to them? If so, please give examples.**

The Bioethics Commission carefully examined the ethics of pre-event MCM research, that is, research undertaken before an event such as a bioterror attack occurs. Such research poses no prospect of direct benefit to research participants because no children are affected by the condition being studied. The Bioethics Commission recommended that, in general, pre-event MCM research only take place if it presents no more than minimal risk to participants, that is, no greater risk than that faced by a healthy child in daily life or at a routine medical examination. This risk limit operates in addition to other participant protections, such as requirements for parental permission and meaningful child assent. Under extraordinary circumstances, research posing additional risk may be ethically permissible; in the case of pre-event pediatric MCM research, the Bioethics Commission recommended that such risk be limited to a minor increase over minimal – a level that is still very limited and poses no substantial risk to participants' health or well-being.

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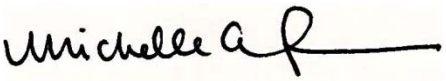
Four ethical principles guided the Bioethics Commission's analysis: respect for persons, beneficence, justice, and democratic deliberation. The current U.S. regulations for pediatric research protections – 45 C.F.R. Part 46, Subpart D and 21 C.F.R. Part 50, Subpart D – also informed the Bioethics Commission's work.

The Bioethics Commission concluded *Safeguarding Children* by calling for "an ongoing national conversation in order to ensure the highest standards of protection for children that reflect an unwavering commitment to safeguard all children *from* unacceptable risks in research and *through* research that promotes their health and well-being." I am pleased that the Bioethics Commission can contribute to a broader international conversation as well.

With best regards,



Michelle Groman, J.D.
Associate Director

cc: Amy Gutmann, Ph.D.
Chair