12 March 2019
Dr. Kevin Smith Health Network
President & CEO, University
kevin.smith@uhn.ca

Dear Dr. Smith,

We write in response to your request dated March 18, 2019 that we disclose to Dr. Baker the identifying information of the patients whom we reviewed as part of our research – specifically, as described in the letter to us from Mr. Toppings dated February 28, 2019, providing "the names and/or medical record numbers of the patients identified in your research to whom your research indicated potential concern."

Mr. Toppings indicated that he believes there is no legal impediment to our providing such information under the *Personal Health Information Protection Act, 2004* since "custodians such as UHN, the Hospital may use PHI about individuals 'for the purpose of risk management, error management or for the purpose of activities to improve or maintain the quality of care or to improve or maintain the quality of any related programs or services of the custodian."

This, in effect, asks us to disclose which specific identified patients consented to participate in our research study. We believe that this information is:

1) information that we are not at liberty to share; and

2) information that is not that is necessary for you to fulfill what you have rightly identified as your responsibility to "look into all quality concerns when raised and ensure appropriate measures are taken to address those concern."

We understand that it is not ethically defensible for us to disclose this information because doing so would:

1) breach the promise we made to research participants to keep the information confidential;

2) place the research participants at risk of retribution for having participated in the study; and

3) create anxiety among research participants that they will face negative consequences for having consented to be in the study (because the fact of them being identified as research participants to Dr. Baker would obviously have to be disclosed to them).

Furthermore, you can meet your legal and ethical responsibilities without us breaching our ethical obligations. That is, as custodian of the data for all patients in the Red Blood Cell Clinic, you can direct the Clinic to release to Dr. Baker the records for all patients prescribed deferiprone between 2009 and 2005, and thereafter. This way:

1) the research participants will not be identified; and

2) the quality of care of all patients exposed to deferiprone can be assessed and appropriate remedial action can be taken (in respect of the care of individual patients, the delivery of deferiprone through a research protocol and/or Special Access Programme, and the sharing of any information about adverse events with Health Canada).

As you noted in your letter to us, “we want to ensure that nothing and no one is missed.” The way to ensure that is for Dr. Baker to review the records (without identifying information) of all patients who received deferiprone, not just those who participated in our research study. Those can be accessed through Dr. Ward. A problem with the use of deferiprone was identified through our study. A thorough review of the care provided to all patients who received deferiprone through the Clinic is required (including whether patients gave fully informed consent to deferiprone, a then-unlicensed drug, and were appropriately monitored, whether the drug was provided through an REB-approved protocol or through Health Canada’s SAP program, and whether all requirements of the REB/SAP were met).

We are glad to see that UHN is taking this issue seriously and is commissioning an independent review. We will fully cooperate with this review within the constraints of our legal and ethical obligations to the research participants.

Yours sincerely,

Brenda L. Gallie, MD, FRCSC, CM, OOnt
Head, Retinoblastoma Programs,
Hospital for Sick Children and Alberta Children’s Hospital;
Associate Scientist, TECHNA Institute, UHN;
Professor, Ophthalmology, Medical Biophysics, Molecular Genetics, University of Toronto.
555 University Ave, Toronto M5G 1X8
brenda@gallie.ca

Nancy F. Olivieri, MD, MA, FRCPC
Professor, Pediatrics, Medicine and Public Health Sciences,
University of Toronto, Canada;
Senior Scientist, Toronto General Hospital, UHN.
200 Elizabeth Street, EN 13-222,
Toronto, Ontario Canada M5G 2C4
nancy@hemoglobal.org

CC: Dr. Michael Baker