



May 15, 2019

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

Dr. Brian D. Hodges
EVP and Chief Medical Officer
brian.hodges@uhn.ca

Dear Drs. Smith and Hodges

We acknowledge your email of May 15, 2019. Like the previous email your email was not copied to Dr. Nancy Olivieri.

Your reply does not address our concerns about our duty and responsibility to inform patients consented to our research study. Our research found that patients had been adversely affected by their treatment with unlicensed deferiprone. Our ethical obligation to inform each consented patient is unambiguous. The *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* [TCPS2], Article 3.4 states: "Researchers have an obligation to disclose to the participant any material incidental findings discovered in the course of research." [<http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter3-chapitre3/>]

Similarly, The Canadian Medical Protective Association (<https://www.cmpa-acpm.ca/en/research-policy/public-policy/disclosing-harm-from-a-healthcare-delivery-event>) states: "Patients expect to be informed about harm they have experienced, whatever the reason for it, and this information needs to be delivered in a caring manner. Effective communication with patients and the healthcare team can improve patient outcomes and satisfaction. Conversely, failures in communication may lead to patient harm, misunderstandings, complaints, and lawsuits."

The UHN prescribers of deferiprone (Drs. Ward, Kuo, and Yeo and others) and the UHN Administration and legal teams (who were aware of their prescribing practices) also have ethical and legal obligations to ensure that all patients are informed about any harms suffered. We have no way to ascertain whether these patients who consented to our study were appropriately informed about harms suffered but this is not relevant, because neither these physicians nor these administrators were collaborators in our research, and neither is in a position to disclose our findings to individual patients.

We have a separate duty to disclose. You have an obligation to ensure that we are able to do so.

We trust you will facilitate this. We look forward to your reply by Wednesday May 22.

Yours sincerely,

A handwritten signature in black ink that reads "Brenda L. Gallie".

Brenda L. Gallie, MD, FRCSC, CM, OOnt
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A handwritten signature in black ink that reads "Nancy F. Olivieri".

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