

**Institutional Review
Board Office**

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NORTHWESTERN
UNIVERSITY

June 17, 2011

S. Albert Edwards
16 Yorkshire Drive
Lincolnshire, IL 60069

Dear Mr. Edwards:

I am in receipt of your letter dated March 8, 2011 to Northwestern University's Institutional Review Board (IRB). In your letter you stated that you received a Myxo-ETlogix model 5100 ring implanted by Dr. Patrick McCarthy on February 14, 2007 and inquired whether your patient data from that procedure was used in the publication you enclosed, *Initial clinical experience with Myxo-Etlogix mitral valve repair ring*. Upon review, we determined that your patient data was used in the article. We also learned that you declined consent to having your information collected in the "Cardiac Surgery Outcomes Registry" ("the Registry") maintained by Dr. McCarthy and his research study staff. This prompted my office to investigate why your data was used in the aforementioned article.

In the article you included with your letter, your data was presented in the aggregate, meaning your identity and any identifiable information about you was not published. This is true of all data collected retrospectively in the Registry. Even though your identity is secure, it is the mission of the IRB to safeguard the rights and welfare of human subjects involved in research. I have ensured that your data is no longer included in the Registry. I have also spoken with Dr. McCarthy's research personnel about this issue and additional procedures have been put into place to ensure that a similar incident does not happen again. Northwestern University values the integrity of our research community and upholds the highest standards of credibility and trustworthiness of research conducted by its members. On behalf of Northwestern University, I apologize for the indiscretion. It is of the utmost importance that your decision to decline participation in the Registry be respected.

Please feel free to contact me if you wish to discuss this further and thank you for bringing this important issue to our attention.

Sincerely,

A handwritten signature in cursive script, appearing to read "Heather J. Gipson".

Heather J. Gipson, JD, MA
Director, Institutional Review Board Office