FDA FOIA Documents: Circuit Court Filings Confirm Termination of Human Heart Study at Northwestern University

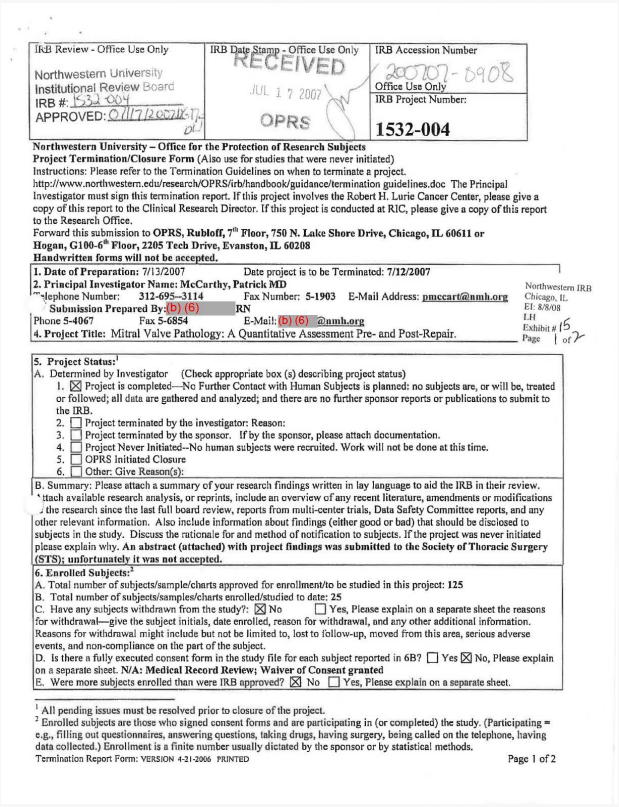
FDA FOIA documents reveal evidence in a ten year old case providing a legal pathway to request for a new trial. Press release provides links for US Citizens.

SHEBOYGAN, WISCONSIN, USA, May 13, 2019 /EINPresswire.com/ -- The final clues are falling into place in a 12-year-old mystery about how patient protections were bypassed during open heart surgery for hundreds of patients and published in the American Association of Thoracic Surgeons Journal.

The Model 5100 heart valve ring was implanted into nearly 700 patients without their consent or approval from the Food and Drug Administration.

Documents recently obtained through a Freedom of Information Act request outline how this practice escaped regulatory notice and notice of the Judge and plaintiff's attorney in the civil case 08-L-012426 Circuit Court of Cook County.

Link to Public Court Documents: https://www.scribd.com/document/401704498/PlaintiffPetition1401-02222019



IRB Review - Office Use Only
Northwestern University
Institutional Review Board
IRB #: 1532-004
APPROVED: 07/17/2007

IRB Date Stamp - Office Use Only
RECEIVED
JUL 17 2007
OPRS

IRB Accession Number
20070707-0908
Office Use Only
IRB Project Number:
1532-004

Northwestern University – Office for the Protection of Research Subjects
Project Termination/Closure Form (Also use for studies that were never initiated)
Instructions: Please refer to the Termination Guidelines on when to terminate a project.
http://www.northwestern.edu/research/OPRS/irb/handbook/guidance/termination guidelines.doc The Principal Investigator must sign this termination report. If this project involves the Robert H. Lurie Cancer Center, please give a copy of this report to the Clinical Research Director. If this project is conducted at RIC, please give a copy of this report to the Research Office.
Forward this submission to **OPRS, Rubloff, 7th Floor, 750 N. Lake Shore Drive, Chicago, IL 60611 or Hogan, G100-6th Floor, 2205 Tech Drive, Evanston, IL 60208**
Handwritten forms will not be accepted.

1. Date of Preparation: 7/13/2007 Date project is to be Terminated: **7/12/2007**
2. Principal Investigator Name: McCarthy, Patrick MD
Telephone Number: 312-695--3114 Fax Number: 5-1903 E-Mail Address: pmccart@nmh.org
Submission Prepared By: (b) (6) RN
Phone 5-4067 Fax 5-6854 E-Mail: (b) (6) @nmh.org
4. Project Title: Mitral Valve Pathology: A Quantitative Assessment Pre- and Post-Repair.

Northwestern IRB Chicago, IL EI: 8/8/08 LH Exhibit # 15 Page 1 of 2

5. Project Status:[1]
A. Determined by Investigator (Check appropriate box (s) describing project status)
1. ☒ Project is completed—No Further Contact with Human Subjects is planned: no subjects are, or will be, treated or followed; all data are gathered and analyzed; and there are no further sponsor reports or publications to submit to the IRB.
2. ☐ Project terminated by the investigator: Reason:
3. ☐ Project terminated by the sponsor. If by the sponsor, please attach documentation.
4. ☐ Project Never Initiated--No human subjects were recruited. Work will not be done at this time.
5. ☐ OPRS Initiated Closure
6. ☐ Other: Give Reason(s):

B. Summary: Please attach a summary of your research findings written in lay language to aid the IRB in their review. Attach available research analysis, or reprints, include an overview of any recent literature, amendments or modifications to the research since the last full board review, reports from multi-center trials, Data Safety Committee reports, and any other relevant information. Also include information about findings (either good or bad) that should be disclosed to subjects in the study. Discuss the rationale for and method of notification to subjects. If the project was never initiated please explain why. **An abstract (attached) with project findings was submitted to the Society of Thoracic Surgery (STS); unfortunately it was not accepted.**

6. Enrolled Subjects:[2]
A. Total number of subjects/sample/charts approved for enrollment/to be studied in this project: **125**
B. Total number of subjects/samples/charts enrolled/studied to date: **25**
C. Have any subjects withdrawn from the study?: ☒ No ☐ Yes, Please explain on a separate sheet the reasons for withdrawal—give the subject initials, date enrolled, reason for withdrawal, and any other additional information. Reasons for withdrawal might include but not be limited to, lost to follow-up, moved from this area, serious adverse events, and non-compliance on the part of the subject.
D. Is there a fully executed consent form in the study file for each subject reported in 6B? ☐ Yes ☒ No, Please explain on a separate sheet. **N/A: Medical Record Review; Waiver of Consent granted**
E. Were more subjects enrolled than were IRB approved? ☒ No ☐ Yes, Please explain on a separate sheet.

[1] All pending issues must be resolved prior to closure of the project.
[2] Enrolled subjects are those who signed consent forms and are participating in (or completed) the study. (Participating = e.g., filling out questionnaires, answering questions, taking drugs, having surgery, being called on the telephone, having data collected.) Enrollment is a finite number usually dictated by the sponsor or by statistical methods.
Termination Report Form: VERSION 4-21-2006 PRINTED Page 1 of 2

FDA FOIA DOCUMENT FILED IN CIRCUIT COURT OF COOK COUNTY

Northwestern's defense attorney from the law firm Anderson Rasor stated in Judge Gomolinski's Chicago courtroom on Dec. 6, 2013 that the federal protocol 1532-004 had nothing to do with a published study on the heart valve.

https://www.scribd.com/document/409805204/120613-motion

> The Truth Shall Set you Free as posted in the Lobby of the Chicago Tribune Building"
>
> *John 8:32*

But the new FOIA documents confirm that after the Federal FDA Inspection, 1532-004 was the study to test the Myxo Ring. The documents also confirm that there was no documentation provided to the University confirming the FDA approval status of the device during the testing.

https://www.scribd.com/document/407458228/FOIA-FDA-12-18-2018-IHS

"He (the surgeon) was putting it into patients, seeing how it worked, and not telling them," Obermeier's attorney, Adrwin Boyer, said during opening statements of the 2016 court trial in

Cook County, according to Fox 32 in Chicago.

Meanwhile, a cardiologist who removed herself from the Model 5100 device study when she realized patients hadn't given their consent, published a report on May 4, 2019, to highlight key facts and documents in the case:

•Patients began receiving the controversial heart valve ring in 2006.
•Testing of the device was officially closed by Northwestern University officials as of June 2006, but the final publication of the clinical study published in the American Association of Thoracic Surgery's premier journal in July 2008 reveals that the study continued without patient consent and without the university approval until November 2007 See attached FDA FOIA document.
•A press release on Dec. 4, 2008, confirmed the first of many Senate Finance and Senate Judiciary investigations into the Model 5100.
•United States Sen. Charles Grassley (IA) requested evidence as part of the Senate Investigation .

Over the six-year investigation, the documents, responses and letters were reviewed by Dr. Nalini Rajamannan, the cardiologist who removed herself from the Model 5100 study.

Rajamannan's report, The Myxo File X and the Myxo Report, offers a comprehensive look at the Senate Finance and Senate Judiciary Investigations from 2008-2014 for the 667 heart valve patients, media, regulators, lawmakers and patients' rights advocates.

The Myxo File X, published on Amazon.com, also provides an in-depth analysis by Dr. Rajamannan, an eye-witness to the human experiments, regarding the release of responses sent to the Senate.

Following is a link to the FDA FOIA documents released on December 18 2019, on the eve of FDA meeting with the heart valve specialist Dr. Rajamannan:

https://www.scribd.com/user/383243128/Nalini-Rajamannan

Dr. Nalini Rajamannan is a heart valve expert in the field of cardiovascular medicine. She has been researching heart valve disease for 31 years. She earned her undergraduate science pre-professional degree from the University of Notre Dame, her Medical Doctorate from Mayo Medical School and her post-graduate training in Internal Medicine and Cardiology at the Mayo Clinic. She also worked at the Mayo Clinic as a staff consultant in Internal Medicine. Currently, she practices consultative medicine specializing in Cardiac Valvular Heart Disease at Most Sacred Heart of Jesus Cardiology and Valvular Institute, WI.

Visit https://www.sacredcardiology.com/ for more information about Most Sacred Heart of Jesus Cardiology and Valve Institute

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