CITATION: Stirrett v. Cheema, 2018 ONSC 2595
COURT FILE NO.: 06-CV-305803PD1
DATE: 20180809

ONTARIO

SUPERIOR COURT OF JUSTICE

BETWEEN:	)	
	)	
	)	
KAREN STIRRETT	)	*Richard Bogoroch and Toby Samson*, for the Plaintiff
Plaintiff	)	
	)	
– and –	)	
	)	
ASIM NAZIR CHEEMA, TEJ NARENDRA SHETH, and BRADLEY STRAUSS	)	*William D. Black and Christine Wadsworth*, for the Defendants
Defendants	)	
	)	
	)	**HEARD: March 20 to April 18, 2018**

REASONS FOR DECISION

G. DOW, J.

[1] The plaintiff seeks to recover damages from the defendants on the basis one or more of them breached their fiduciary duty to the deceased spouse of the plaintiff. The plaintiff submitted the remedy for a breach of a fiduciary duty was equitable relief. The *Courts of Justice Act*, RSO, 1990 c. C.43, section 108(2)11. requires equitable relief be determined without a jury.

[2] The plaintiff also sought to recover from the defendants in negligence. On that cause of action, this matter proceeded to trial with a jury beginning on March 20 and concluding on April 18, 2018. The plaintiff is the spouse of the deceased, David Stirrett. David Stirrett died on February 12, 2005 as a result of undergoing an angiogram performed by the defendants, Dr. Cheema and Dr. Sheth. The angiogram was conducted because David Stirrett had become a participant in what was called the STREAM study on June 11, 2004. The jury found (only) Dr. Strauss to be negligent identifying four particulars:

a) the sample size should have been changed in the protocol from 240 patients to 100 patients;

b) the Data Safety Monitoring Board was never set up as set out in the protocol;

c) the consent form was never updated with the new sample size from 240 patients to 100; and

d) no protocol deviations were submitted to the REB (Research Ethics Board) based on the following information above.

[3] However, the jury also found that the negligence of Dr. Strauss was not the cause of David Stirrett undergoing the angiogram on February 10, 2005.

[4] David Stirrett, born January 12, 1951, was an overweight, non-insulin dependent, Type II diabetic, and smoker that began to have chest pain and shortness of breath in early 2004. His family physician referred him to a cardiologist who arranged for an angiogram to be done on June 7, 2004 at Scarborough Centenary Health Centre. The results revealed a 90 percent blockage or "stenosis" in his left circumflex artery. This is a dominant artery supplying blood to one's heart. The evidence at trial was any stenosis over 50 percent was significant and over 70 percent was severe. I would infer this is why it was only four days later he was scheduled for angioplasty at St. Michael's Hospital in downtown Toronto. Angioplasty is the same basic procedure used as in an angiogram. That is, a wire or catheter is inserted into an artery from the wrist or groin and is moved to where the blockage has occurred. The blockage is stretched or pushed out of the way by an expandable balloon at the end of the catheter or by placement of a metal sleeve or stent expanded within the artery or both.

[5] Scientific research on humans has evolved to the point that any study proposed needs to comply with the Tri-Council Policy Statement regarding ethical conduct for research involving humans. The Canadian Institutes of Health Research, the Natural Sciences and Engineering Research Council of Canada and the Social Science and Humanities Research Council of Canada have agreed on how such research must proceed in this document (Exhibit 1(a), Tab 93).

[6] The field of cardiology has evolved over the last 30 years with regard to the treatment of blocked arteries from invasive bypass surgery to less invasive balloons and stents. In 1999, Dr. Strauss participated in the development and submitting of the STREAM study to the Heart & Stroke Foundation for funding. It was reviewed and rejected. It was resubmitted in 2001 and granted funding in the amount of $193,870.00 per year for three years. The purpose of the study, or "protocol" was to determine if "intensive control of glucose levels with insulin" would reduce the observed problem of restenosis, particularly in diabetics.

[7] Interventional cardiologists, the sub-specialty of cardiologists performing surgical procedures such as angioplasties, had observed restenosis occurred at a higher rate in diabetics than non-diabetics. It was theorized if a non-insulin dependent diabetic's blood sugar levels could better controlled and reduce stenosis, a better path of treatment and care would result.

[8] As part of developing the project and obtaining the requisite approval and funding, the protocol set out specific parameters, the key ones for this trial and my purposes being:

a) a sample size of 240 participants was required to ensure there were enough participants for the results required to meet statistical validity requirements but would not put in danger or put at risk more persons than necessary;

b) a Data Safety Monitoring Board would be set up. This is a group with medical, ethical and statistical expertise that would receive and review the data as it became available to "oversee the progress of the trial and monitor the safety of the intervention" (see Item 11 of the Protocol or Exhibit 1(a), Tab 34, page 109);

c) the Consent form to be signed and understood by participants would reflect the Tri-Council Policy Statement of "full and frank disclosure of all information relevant to free and informed consent" (see Article 2.4 or Exhibit 1(b) at Tab 93, page 383).

[9] David Stirrett attended St. Michael's Hospital on June 11, 2004 to undergo angioplasty on an urgent basis. That day, before this procedure, he was recruited by Anne Fry, a registered nurse at St. Michael's Hospital on behalf of Dr. Strauss who was the principal investigator for the STREAM study at this hospital. She testified becoming aware that David Stirrett was a possible participant by reviewing records of individuals coming to the hospital for treatment. She agreed it was a very good possibility David Stirrett had no idea he was to be recruited when he arrived at the hospital. He would not have been called in advance.

[10] Two key aspects of participating was being prepared to self-inject insulin and to undergo a follow-up angiogram six months following an initial procedure. It was not explained to David Stirrett that the study was having difficulty finding qualified participants.

[11] The letter dated March 14, 2001 from the Heart and Stroke Foundation which granted funding (Exhibit 1(a), Tab 33) proposed funding in the amount of $193,870.00 per year for three years. This was provided for the anticipated 240 participants. Funding for the second and third year was conditional on funds being available and on progress reports being submitted. The lead investigating doctor was Dr. Natarajan at Hamilton Health Sciences. Other hospitals and site investigators such as St. Michael's and Dr. Strauss would also be participating.

[12] Each hospital that participates in research on humans has in place its own procedural safe guards, chiefly what are called Research Ethics Boards. The Tri-Council Policy Statement states these Boards shall consist of at least five individuals with expertise in the fields of medicine, ethics and statistics. The principal investigator at the hospital site, such as St. Michael's, is required to provide annual updates on the research it is conducting. The Research Ethics Board provides approval to the doctor or doctors involved for the research to commence and continue.

[13] The STREAM study was an attempt to determine if strict control of insulin levels and non-insulin dependent diabetics could reduce restenosis in patients treated for life threatening blockages by the placement of stents within their arteries. The participants were split into two groups. The first group was trained in how to administer insulin to better control their blood sugar levels. The second group or "best medical care" did not receive a supply of insulin but

were educated and encouraged to follow exercise and dietary recommendations. The way to determine if there was any change in the amount of restenosis was to conduct a follow-up angiogram and intravascular ultrasound six months following the implantation of the metal stent (see Exhibit 1(a), Tab 38 at page 163). That is, this medical procedure, with its inherent risk being approximately one in one thousand of a serious complication such as heart attack, stroke or death, was not to be done as part of regular clinical practice but only for medical research purposes.

[14] There was delay in the study proceeding due to drafting requisite legal documents, the closure of St. Michael's Hospital to new patients in the summer of 2003 due to the SARS outbreak, and securing a supply of insulin along with the needles required to inject it. The slow enrollment resulted in steps being taken to increase the number of hospitals recruiting participants and to amend the protocol to look at more than one lesion or area treated in a single study participant.

[15] However, as confirmed by the letter dated September 23, 2003 (Exhibit 1(b) at Tab 53, page 243), the failure to secure sufficient participants in a timely manner resulted in the Heart & Stroke Foundation deciding not to fund the third year of the study. That letter terminated funding at the end of two years. The amount of funding approved but not yet accessed was $171,942.00 and it was to remain available. The submission by Dr. Strauss to the St. Michael's Hospital Research Ethics Board on February 9, 2004 for annual approval of the study to continue in 2004 noted only 55 participants had been enrolled at that time, 20 of which were from St. Michael's Hospital (Exhibit 1(b), Tab 58). The letter of September 23, 2003 also contains the phrase "Since the STREAM study will be closing,...".

[16] Despite the termination of funding and the inability to attract a sufficient number of participants to produce statistically valid results, Dr. Strauss decided to continue to recruit participants in 2004. He and Dr. Natarajan co-authored a letter/email dated January 26, 2004 (see Exhibit 1(b), Tab 56 and Exhibit 26) to the study Site Investigators and other involved persons advising that the response to low recruitment, (then at 55) and the withdrawal of funding, was to continue the study and recruitment until one hundred participants was reached. This decision was not communicated to the St. Michael's Hospital Research Ethics Board in the annual approval form they required. Dr. Strauss admitted on his evidence the number of participant's "likely should have been changed" in the STREAM study consent form at this point.

[17] In response to the January 26, 2004 letter/email, Dr. Eric Cohen, who is identified on the STREAM study letterhead as being on the "Steering Committee" along with Dr. Strauss responded by email that it "will be important to restate objectives for the study" and "I think our REB would need to know about a significant re-design". In addition, Dr. Peter Seidelin, who is also identified on the STREAM study letterhead emailed Dr. Strauss that he agreed with Dr. Cohen stating "our REB must be informed of this change in sponsorship and protocol. I would be happy to forward such a message and a justification for continuing enrollment from the central co-ordinating office to RREB. Please send such a message at the earliest opportunity". Dr. Strauss testified at trial that he disagreed with the positions set out by Dr. Cohen and Dr. Seidelin.

[18] No changes were made to the consent form before it was presented to David Stirrett on June 11, 2004. That consent form, (Exhibit 1(a), Tab 11) makes it clear, on page 2, the request is "to participate in the study of about 240 patients similar to yourself". It is also clear in stating (at page 3) that "the follow-up angiogram and intravascular ultrasound at six months is not part of regular clinical practice but rather is part of the research trial. Participation was voluntary and the individual could withdraw at any time "without penalty".

[19] Anne Fry testified the Heart & Stroke Foundation involvement in the study was part of her presentation to a potential participant. The consent form identifies the Heart & Stroke Foundation of Ontario (at page 5) and that they, in addition to the study doctor, could stop participation without the participant's consent "if you need additional treatment, cannot follow the study plan, experience a serious side effect or a study-related injury, or for administrative reasons". Anne Fry testified she did not advise David Stirrett the Heart & Stroke Foundation was no longer sponsoring the study or that recruitment of participants had been reduced to 100.

[20] The consent form also stated under the heading "NEW INFORMATION" that "Your doctor will inform you of any new information about the study that might develop during the course of this research and might influence your willingness to participate in the study". The evidence of David Stirrett's brother was that the Heart & Stroke Foundation was something David Stirrett had previously supported as their father had suffered from heart disease, had undergone bypass surgery, was diabetic and a smoker.

[21] It should also be noted that a Data Safety Monitoring Board was never established as indicated in the protocol submitted to and approved by the Heart and Stroke Foundation. Dr. Strauss admitted in his evidence that this was also not made known to the Research Ethics Board at St. Michael's Hospital. His explanation for including it in the protocol was the possibility of an adverse reaction to administering insulin by test group participants. Having low blood sugar or "hypoglycemia" was defined by the defendants' interventional cardiologist expert witness to include "sweating, trembling, anxiety, dizziness, confusion and difficulty speaking" (see Exhibit 21).

[22] There was evidence that the need for the number of participants in a study involving human research is determined by a statistical mathematician who applies his or her knowledge and skill to medical issues. They are known as biostaticians. They evaluate the number that is required to ensure the result is reliable rather than inconclusive or possibly misleading. The calculation builds into it a certain percentage of participants that are anticipated will drop out. In the STREAM study, this was 20% or 48 persons. It also ensures no more than necessary are included given research on human involves risk of harm and this must be minimized. The purpose is to have a study large enough to obtain data that can detect the smallest clinically significant difference. Dr. Strauss admitted reducing the participants meant this could no longer occur. The STREAM study, which when it concluded, had only 78 participants (of which David Stirrett was number 73) and 96 lesions or "data points", and could only detect larger differences.

[23] It should also be noted that the stents being studied were of the "bare metal" variety. Dr. Strauss testified a new generation of drug eluting stents had been invented and had begun to be used by 2002 with initial results showing greatly reduced restenosis. The drug eluting stents

were significantly more expensive than bare metal stents and only being used in about 20% of cases. Dr. Strauss admitted the circumstances had changed from when the study was first planned in 1999 but the use of insulin to reduce restenosis was possibly a less expensive way to achieve this result.

[24] Dr. Sheth and Dr. Cheema were the interventional cardiologists that performed the angioplasty and intravascular ultrasound on David Stirrett on June 11, 2004. As of that date, Dr. Sheth was in his final month as a resident. He was performing procedures under the guidance and direction of Dr. Cheema that day. Neither were investigators in the STREAM Study at the time but were scheduled to perform David Stirrett's angioplasty. They were responsible for and obtained David Stirrett's written consent for the procedure independent of the consent signed by David Stirrett to participate in the STREAM study. Only Dr. Sheth witnessed the June 11, 2004 consent form and he had no recollection of his conversation with David Stirrett regarding signing the consent or performing the procedure.

[25] Anne Fry testified she would have advised the catheter operating laboratory staff of David Stirrett's participation in the STREAM study so they would take precise recordings which would be duplicated in the follow-up angiogram and intravascular ultrasound. Dr. Cheema similarly had no independent recollection of contact with David Stirrett on June 11, 2004 or the conduct of the procedure. The June 11, 2004 angioplasty and STREAM study testing proceeded without incident.

[26] Anne Fry, under the direction of Dr. Strauss, was responsible for the follow-up care of David Stirrett. She met him at the hospital on September 15, 2004 for an estimated 20-30 minutes and the records confirmed this occurred. She also confirmed he was booked for the follow-up angiogram to proceed on November 25, 2004. This was the date Dr. Cheema was doing procedures and was deliberate for continuity of care. The date was rebooked to December 9 for unknown reasons and again to February 10, 2005. Again, this was when Dr. Cheema and Dr. Sheth were doing procedures.

[27] The fact February 9, 2005 was eight months after June 11, 2004 was contrary to the protocol requirement of it being done within "6 months ($\pm$ 2 weeks)" (see Exhibit 1(a), Tab 34 at page 106). Anne Fry testified this was not something requiring strict compliance and only a deviation form needed to be completed.

[28] On February 10, 2005, Dr. Sheth began the procedure on David Stirrett in the catheter operating laboratory. Dr. Sheth began to have difficulty placing the catheter in the optimal position. He asked for help and Dr. Cheema came in and took over. Dr. Cheema extracted the catheter being used and reinserted a different catheter. Soon thereafter, a dissection was noted to have occurred. This was a life threatening complication and immediate efforts were made to save David Stirrett's life.

[29] Dr. Horlick, in his capacity as an expert witness described dissection as the separation of the inner and middle layers of the muscular tissue of the artery walls which blocks blood flow and can cause a heart attack. David Stirrett was stabilized but only on life support. His organs

began to fail and he was taken off life support by his family on February 12, 2005 and died that same day.

[30] Both sides called biostaticians about the appropriateness of continuing the STREAM study once funding was discontinued due to insufficient recruitment. This prevented obtaining the data necessary to obtain results which could detect the smallest clinically significant difference. Dr. Donner, on behalf of the plaintiff, opined the study should have been stopped because it could no longer fulfill its primary objective and had not specified any secondary objectives.

[31] Dr. Willan, on behalf of the defendants, opined there are no hard and fast rules about terminating a study once it is acknowledged it would not be able to reach its primary objective due to insufficient participation or data points. This led to evidence about the value of smaller, incomplete studies being reported so the data can be combined with other, subsequent studies. Dr. Willan opined this had merit but Dr. Donner expressed concern about incorrect interpretation of conclusions.

[32] The STREAM study results, which were inconclusive, were eventually published in 2012. Dr. Strauss testified the results have been cited in other published studies subsequently.

[33] The plaintiff called a professor of philosophy, Arthur Schafer, whose career has focused on ethical issues particularly in the medical field. He was tendered to give evidence as an ethicist. Specifically, he testified about the information David Stirrett was given before agreeing to participate in the STREAM study. He admitted in cross-examination on his qualifications that he had no medical expertise or training in biostatistics. I qualified him to give expert evidence as an ethicist.

[34] His evidence was valuable in putting into context the procedure to be followed when conducting medical research on humans. As stated in the Tri-Council Policy Statement, it is necessary to protect a participant's dignity and safety. This is also why Research Ethics Boards exist. Medical research on humans necessarily involves a risk of harm. Greater risk may be tolerated to obtain more valuable outcomes. The decision on whether such research can proceed must be made by bodies independent of the group proposing the research (or principal investigators). Similarly, to quote article 2.4 of the Tri-Council Policy Statement, the prospective subject must be provided "full and frank disclosure of all information relevant to free and informed consent". (Exhibit 1(b), Tab 93 at page 383).

[35] To that end, Professor Schafer opined that anything which would influence the decision of a prospective patient or participant should be disclosed. Further, the patient or participant should be updated on new information as it develops. This is in accord with the participant's right to withdraw at any time. The requirements for conducting research on humans are detailed in the Tri-Council Policy Statement and Professor Schafer opined Dr. Strauss failed to comply with the following requirements:

a) the failure to appoint a Data Safety Monitoring Board which was required by the protocol and the failure to advise the Research Ethics Board that this had not been

done given the Research Ethics Board likely relied on its existence as part of their granting approval for the research to proceed at St. Michael's Hospital;

b) the failure to update the consent form drafted and presented to David Stirrett to sign. It was misleading as of June, 2004, particularly with regard to the decision having already been made to reduce the goal for the number of participants be decreased from 240 to 100 and which Dr. Strauss admitted "likely should have been changed";

c) the failure to accurately communicate to David Stirrett the end of funding by the Heart & Stroke Foundation; and

d) the effort to obtain David Stirrett's consent on the morning he was scheduled to undergo what I have inferred was urgent angioplasty rather than doing so even one day before so he could reflect on his decision and discuss it with others.

[36] Professor Schafer also opined patients are generally deferential to their treating doctors and would be concerned that their declining to participate in a study would be resented by the doctor. It should also be noted, in cross-examination, Professor Schafer acknowledged David Stirrett had eight months to reflect on whether to undergo the follow-up angioplasty.

Analysis

[37] The first issue is to determine is that a finding of fiduciary duty is equitable relief and the requirement it be determined by me as the trial judge. I accept the plaintiff's submissions in this regard. In addition to Section 108(2)11. of the *Courts of Justice Act, supra*, I rely on the decision of *McDonald-Wright (Litigation Guardian of) v. O'Herlihy*, [2005] O.J. No. 1636 (appeal dismissed) 2007 ONCA 89) and how to proceed where liability is alleged in both tort and breach of fiduciary duty.

[38] The second issue is to determine whether the factual matrix before me raised a fiduciary duty between David Stirrett and Dr. Strauss.

[39] A fiduciary duty can arise in a doctor-patient relationship. The defendants submit this did not occur on the facts as I have found and are described above. The defendants submit that the law only imposes that a fiduciary duty in a doctor-patient relationship when the patient is exploited and points to the decision in *Norberg v. Wynrib*, [1992] 2 SCR. 226 as a clear example. In that case, a young female, addicted to Fiorinal from previous treatments, sought prescriptions from the defendant physician who complied in exchange for sexual encounters with the plaintiff. The reasons of the Supreme Court of Canada were given by three of the seven justices that heard the appeal. While Justice La Forest and Justice Sopinka did not describe in detail when and how a fiduciary duty could arise, Justice McLachlin (as she then was), at paragraph 64 stated, "the most fundamental characteristic of the doctor-patient relationship is its *fiduciary* nature. All the authorities agree that the relationship of physician to patient also falls into that special category of relationships which the law calls fiduciary". Justice McLachlin goes on to state, at paragraph 68 "The fiduciary relationship has trust, not self-interest, at its core, and when breach occurs, the

balance favours the person wronged". This paragraph concludes with the statement "If a fiduciary relationship is shown to exist, then the proper legal analysis is one based squarely on the full and fair consequences of a breach of that relationship".

[40] The description of what constitutes a fiduciary duty routinely starts with paragraphs 39 to 42 of *Frame v. Smith*, [1987] 2 S.C.R. 99 and was summarized by the Supreme Court of Canada in *Hodgkinson v. Simms*, [1994] 3 S.C.R. 377 where, at paragraph 30, concludes that "guidelines constitute indicia that help recognize a fiduciary relationship rather than ingredients that define it".

[41] I also rely on the subsequent statement in paragraph 33 of that decision being, "what is required is evidence of a mutual understanding that one party has relinquished its own self-interest and agreed to act solely on behalf of the other party".

[42] The jury found Dr. Strauss was negligent but, in applying the law of negligence, also concluded the negligence of Dr. Strauss did not cause David Stirrett to undergo the follow-up or for research purposes only angioplasty. I expect they were influenced by the evidence that the risk of serious harm from the procedure was small, being one in one thousand and the logic of it being better to know the extent of restenosis six to eight months following an angioplasty than not. Also the post mortem pathology report (Exhibit 1(a), Tab 28 at page 59) noted 75% restenosis near, if not at, where the bare metal stent was placed.

[43] The defendants submit that the conduct of the physician in *Norberg v. Wynrib, supra* was clearly outside the recognized confines of the doctor-patient relationship. I agree. This is, in part, why I would conclude the claims of fiduciary duty as against Dr. Cheema and Dr. Sheth must fail. In addition, their involvement was limited to conducting the actual procedure and they obtained the usual procedure consent in the usual manner. However, the scope of the relationship between David Stirrett and Dr. Strauss was different. The relationship was one of patient to researcher in addition to doctor and patient.

[44] The case which both parties relied on that reviewed what should occur in patient to researcher circumstances was *Halushka v. University of Saskatchewan* (1965), 53 D.L.R. (2d) 436 (Sask. CA). In that matter, it was found the plaintiff was not provided all relevant information about his undergoing the test of a new drug which was actually an anaesthetic. Contrary to what the plaintiff was told of the test lasting less than a day, the plaintiff suffered a complete cardiac arrest and was hospitalized for 10 days. The court stated, at paragraph 29, "The subject of medical experimentation is entitled to a full and frank disclosure of all the facts, probabilities and opinions which a reasonable man might be expected to consider before giving his consent. The respondent necessarily had to rely upon the special skill, knowledge and experience of the appellants, who were, in my opinion, placed in a fiduciary position".

[45] Counsel for Dr. Strauss relied on the decision of *McDonald-Wright (Litigation Guardian of) v. O'Herlihy, supra* where the jury found the defendant doctor was not negligent. The particulars of negligence in both that case and this case mirrored the alleged breaches of fiduciary duty. The case before me differs by virtue of the jury's finding of negligence on the

part of Dr. Strauss unlike in the action against Dr. O'Herlihy. I accept that I am obliged to accept the findings of the jury, as triers of the facts.

[46] I agree not all duties owed by a doctor to a patient will rise to the level of a fiduciary duty. However, this was medical research on humans where the patient to doctor relationship becomes participant to researcher. I accept not all aspects of the participant to researcher relationship, where it involves research on humans, will rise to the level of a fiduciary duty. In this regard, I rely on Justice Sopinka's comments in the *Norberg v. Wynrib, supra* decision at paragraph 147 "The relationship between a doctor and his or her patient is precisely of this hybrid genre. In *LAC Minerals Ltd, supra*, I also referred to the judgment of Southin J.A. in *Girardet v. Crease & Co.* (1987), 11 B.C.L.R. (2d) 361 (S.C.), which held that a solicitor's failure to use care and skill did not essentially become a breach of fiduciary duty, but rather, the breach could be founded in contract or negligence. Likewise, certain obligations that arise from a doctor and patient relationship are fiduciary in nature; however, other obligations are contractual or based on the neighbourhood principle which is the foundation of the law of negligence. Fiduciary duties should not be superimposed on these common-law duties simply to improve the nature or extent of the remedy".

[47] The obligation of a researcher to the participant when it involves humans is more strict than a doctor to patient relationship. To quote Justice Mc Lachlin in *Norberg v. Wynrib, supra,* at paragraph 65 "the doctor-patient relationship shares the peculiar hallmark of the fiduciary relationship – trust, the trust of a person with inferior power that another person who has assumed superior power and responsibility will exercise that power for his or her good and only for his or her good and in his or her best interests. Recognizing the fiduciary nature of the doctor – patient relationship provides the law with an analytic model by which physicians can be held to the high standards of dealing with their patients which the trust accorded them requires".

[48] I conclude Dr. Strauss had a fiduciary duty to David Stirrett.

[49] The fiduciary duty was to comply with the terms set out in the consent form as drafted and agreed by David Stirrett. The consent form was drafted in accordance with the principles set out in the Tri-Counsel Policy Statement. The consent form required Dr. Strauss to inform David Stirrett of new information "about the study that might develop during the course of this research and might influence your willingness to participate in the study" (at page 5 of the consent form under the heading "NEW INFORMATION"). Dr. Strauss failed to do so as stated in the particulars of negligence given by the jury. In addition, it was apparent or at least contemplated by more than one other source that the study should not continue in its existing format without resubmitting the revised protocol to each participating hospital's Research Ethics Board. The letter from the Heart & Stroke Foundation of September 23, 2003 contemplated the "closing" of the study. The emails of Dr. Cohen and Dr. Seidelin expressly set out their view that the changes required notice and approval by their respective Research Ethics Boards.

[50] While the changes made in the STREAM study from when the consent form was drafted may not have been significant or changed the risk of harm to David Stirrett, it was not something for Dr. Strauss to decide. His obligation, or duty, was to pass on these changes to David Stirrett

(and to the Research Ethics Board) in order to permit them to re-evaluate their previous decision. This would have protected Dr. Strauss from liability.

[51] Dr. Strauss, by his actions failed to give David Stirrett the opportunity to consider, reflect and determine if he should "discontinue participation at any time during the study without penalty" (also from page 5 of the consent form under the heading "RESEARCH SUBJECT'S RIGHTS"). By not providing the information about the STREAM study which varied from the content of the consent form that was explained to David Stirrett on June 11, 2004 and to which Dr. Strauss, as principal investigator at St. Michael's Hospital for the STREAM study agreed, Dr. Strauss breached his fiduciary duty.

[52] Having found a fiduciary duty existed and that Dr. Strauss breached that duty, the third issue is to determine the legal outcome. Counsel for the plaintiff submitted the finding of a fiduciary duty and the breach of that duty removes causation from the analysis on whether there will be recovery as occurs in the determination of negligence followed by causation. I agree.

[53] I rely on the statement of Justice McLachlin in *Norberg v. Wynrib, supra* at paragraph 95, "Equity has always held trustees strictly accountable in a way the tort of negligence and contract have not". In addition, Justice McLauchlin goes on to state, at paragraph 98, "The physician is pledged by the nature of his calling to use the power the patient cedes to him exclusively for her benefit. If he breaks that pledge, he is liable".

Conclusion

[54] The parties advised they have agreed on damages. There shall be judgment in favour of the plaintiff against the defendant, Bradley Strauss in that amount. The action as against Asim Nazier Cheema and Tej Narendra Sheth is hereby dismissed.

Costs

[55] If the parties cannot agree on costs within the next 45 days, they may speak to the trial office about securing a date to make oral submissions before me. I will require written submissions outlining each party's position of no more than 10 double spaced pages in a readable font provided at least seven days in advance. I urge the parties to resolve this final issue.

Mr. Justice G. Dow

Released: August 9, 2018

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Plaintiff

– and –

ASIM NAZIR CHEEMA, TEJ NARENDRA SHETH, and BRADLEY STRAUSS

Defendants

REASONS FOR DECISION

Dow J.

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