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INDEPENDENT COMMISSION AGAINST CORRUPTION

THE HONOURABLE DAVID IPP AO QC

PUBLIC HEARING

OPERATION CHARITY

Reference: Operation E10/0035

TRANSCRIPT OF PROCEEDINGS

AT SYDNEY

ON MONDAY 14 FEBRUARY 2011

AT 10.10AM

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This transcript has been prepared in accordance with conventions used in the Supreme Court.

THE COMMISSIONER: The Commission is investigating whether Sandra Lazarus, her sister Michelle Lazarus and others fraudulently obtained money from the funds of the Royal Hospital for Women and Royal North Shore Hospital by submitting false requisitions and invoices from companies in which Sandra Lazarus or Michelle Lazarus were shareholders when no services were provided. The general scope and purpose of this public inquiry is to gather evidence relevant to the allegations being investigated for the purpose of determining the matters referred to in section 13(2) of the Independent Commission Against Corruption Act. Mr
10 Alexis.

MR ALEXIS: May it please this Commission, I appear as counsel assisting.

THE COMMISSIONER: Yes.

MS SOARS: Commissioner, Soars, S-O-A-R-S, barrister for Ms Lazarus. I seek leave.

THE COMMISSIONER: Yes, you have leave.
20

MR HOGAN: May it please this Commission, Hogan, barrister, I seek leave to appear for Michelle and Jessica Lazarus.

THE COMMISSIONER: Yes, you have leave.

MR HOGAN: Thank you, sir. Yes.

MS FURNESS: Commissioner, with your leave I appear for Northern Sydney Local Health Network, South Eastern Sydney Local Health
30 Network, the New South Wales Department of Health and those employees working within New South Wales Health.

THE COMMISSIONER: Yes, you have leave.

MS FURNESS: Thank you.

THE COMMISSIONER: Mr - - -

MR ALEXIS: Thank you, Commissioner. I propose to open this public
40 inquiry with some details. It principally concerns the conduct of Sandra Lazarus as a research student operating in certain public hospitals of New South Wales and how she procured significant sums of money from the Royal Hospital for Women at Randwick and the Royal North Shore Hospital at St Leonards through various corporate vehicles she controlled. Her younger sister, Michelle Lazarus, controlled one of the vehicles that procured some of the funds and so the inquiry will concern her conduct as well. For convenience I shall refer to Sandra Lazarus throughout this

opening as Ms Lazarus and to Michelle by her first name without of course meaning any disrespect so as to distinguish between the two.

10 It is alleged that Ms Lazarus and Michelle fraudulently obtained moneys from each of these hospitals by submitting false tax invoices for “goods” that either did not exist or were not supplied to those hospitals or for “services” that were not provided. The fraudulent conduct that is alleged involved not only the forging of signatures of a number of medical practitioners from those hospitals on requisition and other like accounting forms that were submitted with the false invoices to the hospitals to facilitate payment but also the making of false representations to hospital and related personnel so as to procure the payments involved.

Although the inquiry will focus on Royal Hospital for Women and the Royal North Shore Hospital it should be understood that the events that I am about to outline with respect to each of those hospitals is not isolated. The Commission has also received reports of similar conduct by Ms Lazarus at St Vincent’s Hospital in Sydney.

20 In broad terms there are two separate parts to the inquiry. The first will examine the means employed by Ms Lazarus and Michelle to procure the funds involved. In short, Ms Lazarus approached senior clinicians at each hospital in the 2007 and 2008 years claiming to be a PhD student in Medicine at the University of Sydney and sought opportunities to conduct clinical research trials of a device known as the Medex M-E-D-E-X, the Medex device on patients as a tool for the diagnosis of cancer.

30 Both the Royal Hospital for Women and the Royal North Shore Hospitals are teaching hospitals and some of the medical practitioners there have conjoin appointments with universities and conduct research in their own areas of expertise which may include the conduct of clinical trials. Having secured the opportunity and in the process obtaining certain privileges at the hospitals which afforded access to critical documents and accounting information, Ms Lazarus and Michelle prepared and submitted the tax invoices that I have referred to on behalf of their corporate entities and procured payments of \$218,350 from the Royal Hospital for Women and payments of \$465,300 from the Royal North Shore Hospital.

40 I will come to some detail in a moment but ultimately the Commission may consider that the evidence discloses such a brazen fraud it should have been readily detected and so the other part of the inquiry will examine how it was that Ms Lazarus was able to gain access to these hospitals’ sensitive documents and to the accounting information and obtain payment of the false invoices over many months without being exposed. There will of course be a question as to the adequacy of the corruption prevention measures available within the public hospital system in New South Wales, both then and now.

The Medex device was first developed in Israel and is a handheld device that measures the electrical impedance of certain dermal-visceral zones of the body. The device absorbs micro-electricity from the soles of the feet and the palms of the hand and measurements are processed via the device software into a portable computer connected to the device which then presents the results in a graphical form. The rationale apparently of the device as a diagnostic tool is that measurements of electrical impedance of specific derma zones are said to reflect corresponding internal organ pathology. The device is reusable and is not invasive. The results can then be interpreted by a doctor trained in the use of the Medex device.

At the relevant time a Perth based company known as Medex Screen (Australasia) Pty Limited held the distribution rights for the device in Australia. There is published literature indicating that the Medex device has been the subject of a number of medical trials in various countries around the world. But there had been no previous trials conducted in Australia.

The inquiry will give evidence that explains how Ms Lazarus came to be involved with the distributor and its related companies and arrangements for the conduct of some of the first trials using the Medex device at Strathfield Private Hospital, Concord Repatriation General Hospital and St Vincent's Hospital.

It was in about November, 2007 that Ms Lazarus was provided with a number of the Medex units, laptop computers and associated equipment to conduct the proposed medical trials at these hospitals by Medex Screen (Australasia) at no cost to her.

Yes, your Honour, may I now cover some detail with respect to the Royal Hospital for Women. It seems that in about late 2007, Ms Lazarus approached Professor Neville Hacker, the director of Gynaecological Cancer Centre at the Royal Hospital for Women with a proposal that she undertake a clinical trial of the Medex device at the hospital under his supervision to determine if the device could detect cervical cancer. Ms Lazarus claimed to be undertaking similar trials at St Vincent's Hospital with respect to prostate cancer and Concord Hospital with respect to lung and breast cancer. I should note that at the relevant time the Royal Hospital for Women form part of the South Eastern Sydney Illawarra Area Health Service established pursuant to section 17 of the Health Services Act 1997 and the role of the Area Health Service will become relevant when we examine procedures for the payment of the invoices.

Apparently Ms Lazarus initially wanted to examine 100 patients as part of her proposed clinical trial, but Professor Hacker recommended to her that a pilot study of only 10 patients be conducted first so as to assess the utility of any larger scale trial. It was in this context that a letter apparently under the hand of Professor Hacker to the Human Resources Department of the hospital had, bearing a date 17 April, 2008 purported to confirm that Ms

Lazarus was to be employed from 7 April, 2008 for a period of one year as a principal hospital scientist in the Gynaecological Oncology Clinic. This together with the execution of various employment and related forms including authorities for criminal record and working with children checks appears to have enabled Ms Lazarus to obtain a security access pass and other privileges to the hospital.

10 In evidence there will also be a letter to Professor Hacker from a company known as Sydvat, S-Y-D-V-A-T Pty Limited signed by its CEO, a Dr Johel Neiron pledging inter alia the sum of \$75,000 for the “Medex Test Cervical Cancer Research at the Royal Hospital for Women.” At the time, Dr Neiron was a co-director of Medex Screen (Australasia). The content of this letter is important because it provided a foundation for Professor Hacker’s belief that any cost associated with any clinical research trial of the Medex device would be covered by funds provided by a sponsor of the trial that was completely external of the hospital. Thus, this arrangement with Ms Lazarus to conduct a pilot study was on the express basis that the hospital would not incur any cost.

20 And of course the basis of that arrangement was not surprising. Whilst the conduct of clinical research trials are important to achieving advances in medical science, the cost of them are usually paid for by the corporate or pharmaceutical world. The limited financial resources of public hospitals in this state does not usually extend to the conduct of speculative clinical trials without the cost being defrayed externally.

30 The evidence before the inquiry will demonstrate, however, that the Royal Hospital for Women did not receive any funds from Sydvat or Medex Screening (Australasia) or indeed from any external sponsor with respect to Ms Lazarus or any clinical research trials being conducted by her. In this regard, the Commission will be taken to the written applications that were prepared by Ms Lazarus in about April of 2008 and submitted to the Human Research Ethics Committee within the Northern Hospitals Network which includes the Royal Hospital for Women, in relation to the proposed clinical trial which made claim that the project was to be funded entirely from external sources. The application in turn identifies the name of the funding provider as, “University PHD Scholarship.” The application also confirms that the Medex advice would be provided free of charge, that is to say that the hospital would not incur any cost with respect to the supply of the
40 Medex device. The Commission will hear that there is a policy directive from the Department of Health of New South Wales that requires all research projects involving humans to be ethically and scientifically reviewed and approved in accordance with the National Statement on Ethical Conduct in Human Research 2007, published by the National Health and Medical Research Council. The policy also requires a site specific assessment. The policy was and is mandatory and was operative from 1 July, 2007. The National Ethics Application Form and the Site Specific Assessment Form prepared and submitted by Ms Lazarus were required by

this policy directive. The ethics application that was submitted came to be considered in the first instance by the Scientific Review Committee of the Northern Hospital Network of the relevant area health service on 13 May, 2008. Professor Hacker was advised by letter dated 25 June, 2008, that the application was deficient and required substantial amendment before being forwarded to the Ethics Committee for ethical review. The evidence will show that no further or amended application was submitted to that Ethics Committee and that no approval was given for any proposed clinical trial of the Medex device at the Royal Hospital for Women. It seems that Ms Lazarus, nonetheless, informed Professor Hacker in about August or September 2008 that she had obtained approval from the Ethics Committee to commence her pilot project using the Medex device to detect cervical cancer. This seems to have led Professor Hacker to refer Ms Lazarus to clinical nurse specialists, Ellen Barlow and Emma Knowland, within the Gynaecological Oncology Outpatient clinic at the hospital to identify possible patients for participation in the trial. Evidence from these nursing specialists will suggest that no more than a handful of patients were referred to Ms Lazarus for possible participation in the clinical trial. Moreover, evidence from Professor Hacker's personal assistant at the time and other personnel will suggest that Ms Lazarus was rarely seen at the hospital when patients that might be suitable for the trial were identified. She was difficult to contact or locate. The Commission will see that this evidence is at odds with the content of the tax invoices generated by Ms Lazarus to the Royal Hospital for Women, which suggest on their face a significant number of, "Tests", being performed on patients, running into a hundred. The first invoice was generated on 14 May, 2008, at least according to its date.

That is the date of the letter from Sydvat to Professor Hacker, to which I have referred. Also there is no report or other documentation available regarding the performance of the private study which publishes the result or any conclusions to be drawn them with respect to the Medex device and the detection of cervical cancer. At that time, the South Eastern Sydney and Illawarra Area Health Service processed purchase orders or requisitions with tax invoices through its accounting payable section. From March 2009, these functions were transferred to the New South Wales Health Support Services, located in Newcastle. The evidence will demonstrate the accounts payable procedure utilised by Ms Lazarus was as follows. First there was the despatch of a Vendor Maintenance Form which created within the Area Health Service accounting system a new vendor or supplier. The system allocated a specific vendor number. This form had to be completed and processed before any payments could be made to a new supplier of goods or services. Ms Lazarus completed these forms for a company known as Medical and Clinical Informatics Consultants Pty Limited, of which she was its sole director and shareholder. She also completed a form for a company known as Wish Consulting Pty Limited, of which Michelle Lazarus was its sole director and shareholder. It appears that the fact of their respective control of these entities was never disclosed to the hospital. Professor Hacker appears to have signed and thereby authorised each of

these forms, but the evidence will raise a question as to the authenticity of what purports to be his signature. These forms were despatched to accounts payable by a facsimile transmission from the Gynaecological Cancer Centre on 11 July, 2008. Next the procedure for the payment of tax invoices required an accompanying requisition or purchase order. Absent a purchase order, a tax invoice received at the Area Health Service accounts payable section should have the relevant Area Health Service requisition form attached to the invoice. That form required three separate signatures from a requesting officer, a delegating officer and an authorising officer. The evidence will show that the requisition forms that accompanied the tax invoices from Medical and Clinical Informatics Consultants and Wish Consulting were all signed by Ms Lazarus as the requesting officer and dated either 11 or 14 July, 2008. At that point in time, Professor Hacker and Associate Professor Donald Marsden, who was then the deputy director of the Gynaecological Cancer Centre at the time, had the delegated authority to sign as the delegating officer. The latter has purported to sign each requisition form, however as the authorising officer, but only Professor William Walters, the Executive Clinical Director at the Royal Hospital for Women, and two other persons, who did not become involved in this matter, from the hospital, had the requisite authority to sign the requisition forms in that capacity. I note that Professor Walters was also the Chair of the Northern Hospital Network Human Research Ethics Committee. The other important aspect of the accounts payable procedure was that the Area Health Service used a cost centre number and an account code to process payments. The cost centre number is the base unit that is used to capture and record a particular department's expenditure. It seems that a separate account was established for the pilot clinical trial to be conducted by Ms Lazarus within the Department of Gynaecological Oncology at the Royal Hospital for Women with a cost centre number of 1-5-2-0-7-0. This was not associated with any trust account into which an external sponsor may deposit funds. Each of the requisition forms and the tax invoices the Commission will see demonstrate that Ms Lazarus used that number when submitting the invoices for payment. In the events that occurred, Ms Lazarus submitted a total of 16 invoices to the Royal Hospital for Women on behalf of Medical and Clinical Informatics Consultants and Wish Consulting. Of those 16 invoices, only 5 were accompanied by executed requisition forms. As noted earlier, there is a question as to the authenticity of what appears to be Professor Hacker's signature on each of these requisition forms. There is a similar question with respect to the signature that purports to be that of Professor Marsden. His evidence is likely to demonstrate that he was well aware at the time that he had no authority to sign as an authorising officer and did not do so. Of the 16 tax invoices, 9 of them, totalling \$148,500, were submitted on behalf of Medical and Clinical Informatics Consultants for what is described as, "Screening equipment, cervical cancer clinical trial." Each tax invoice was for \$16,500, inclusive of GST, which on the face of some of the invoices appears to relate to 50 examination tests. The invoices therefore purport to represent a total of four hundred and fifty tests which the evidence will demonstrate was considerably in excess of the

number of tests to be conducted as part of the pilot or were observed to have actually occurred. Furthermore, there was no basis on which she could charge for screening equipment which had been supplied to her free of charge. The remaining 7 invoices, totalling the sum of \$69,850, were submitted to the Royal Hospital for Women by Ms Lazarus on behalf of Wish Consulting. These appear on their face to relate to, "Clinical trial marketing, cervical cancer", yet there is no evidence that any such marketing was ever requested or provided. Importantly, there is nothing to suggest from the evidence the Commission will hear, that the Royal Hospital for Women had any contractual obligation with either of these corporate entities to pay for any of the goods or services referred to in the invoices. The existence of a contractual obligation appears to have been assumed by those in the accounts payable section who acted to facilitate the payment of them. As I have indicated, 11 of the 16 invoices were not accompanied by an executed requisition form. Each invoice was nonetheless processed by a data entry clerk and customer inquiry officer. There will be evidence to suggest that the clerk was contacted repeatedly by Ms Lazarus in about August of 2008 concerning what she described as the, "Overdue invoices." Ms Lazarus appears to have endorsed the invoices with the goods, with the words, I'm sorry, "Goods received, okay to pay", or, "Okay to pay, overdue", and then despatched them directly to the attention of the clerk. As many of the invoices appeared on their face to be substantially overdue, because of their date, they received prompt processing. The fact that they were processed for payment without an accompanying requisition or purchase order will receive attention in the inquiry in due course. Curiously, two of the invoices for Medical and Clinical Informatics Consultants and two of the invoices for Wish Consulting were dated between 14 March and 14 April, 2008, that is to say, prior to the date of the letter purporting to appoint Ms Lazarus as a principal scientific officer of the hospital and therefore prior to the date Ms Lazarus could have conceivably conducted any of the clinical research trials. Also, according to Professor Hacker, at the time of receiving the letter from the Scientific Review Committee regarding the ethics application in late June when it was claimed that no ethics approval had been obtained, Ms Lazarus had not commenced any proposed clinical trial. Before moving to the events that occurred at the Royal North Shore Hospital, it is convenient here to note that Professor Walters, the Executive Clinical Director at the Royal Hospital for Women, wrote to Ms Lazarus in late December of 2008, requesting an interview to discuss concerns about conduct that had by that stage emerged. Her security card to the hospital was cancelled pending the interview that in due course took place on 3 February, 2009.

By the time of the interview Ms Lazarus had become the sole director and shareholder of a further corporate entity known as Complete Health and Medicine Pty Limited. That company was incorporated on 8 December, 2008. Shortly before the interview a letter dated 2 February, 2009 from Complete Health and Medicine to the "Department of Fundraising" at the Royal Hospital for women was prepared. It represented to the hospital that

entity has the external sponsor of the clinical trials that were said to have occurred at the hospital. A letter attached a bank cheque for \$80,000 to “support the cervical cancer research project at your research institution.” The letter concludes, “we would like to wish Sandra and other researchers involved in this project the very best of luck.”

Of course, the entity known as Complete Health and Medicine did not exist at the time Ms Lazarus submitted the 16 tax invoices to the Royal Hospital for Women, to which I have referred.

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Further evidence concerning an analysis of developing banking records of that entity Medical and Clinical Informatics Consulting will demonstrate that the bank cheque was sourced from funds transferred between each of these corporate vehicles. In the result, however, the Royal Hospital for Women has now recovered 80,000 of the 218,350 that was given.

20

I now come to the Royal North Shore Hospital. Located within the grounds of that hospital at St Leonards is a large clinical research institute known as the Kolling Institute of Medical Research, which is affiliated with the University of Sydney and Northern Sydney and Central Coast Area Health Service. It appears that Ms Lazarus approached Professor Ross Smith at the Royal North Shore Hospital with respect to her proposed PhD studies in 2008 in relation to the use of the Medex device. Professor Smith was and is the post-graduate co-ordinator with the University of Sydney Faculty of Medicine.

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Although he had reservations and suggested to Ms Lazarus that, that she might like to conduct some laboratory research in other areas, he nonetheless agreed to be her primary supervisor with respect to her studies, he recommended that she conduct her research in relation to the Medex device through the Kolling Institute. Professor Smith was told by Ms Lazarus that she had used the Medex device to detect the presence of prostate cancer in patients at St Vincent’s Hospital and have used the device to detect gynaecological cancer at the Royal Hospital for Women.

40

Like Professor Hacker at the Royal Hospital for Women, Professor Smith believed from what Ms Lazarus had told him that any costs associated with the clinical trial of the Medex device would be covered by funds provided by a sponsor that was completely external of the Royal North Shore Hospital.

The evidence will show that Ms Lazarus completed various forms for access to the Northern Sydney Central Coast computer Network, email and internet registration on 21 and 22 October, 2008. And some of these forms were signed by Professor Smith. She also obtained an identification badge. As events transpired however, Professor Smith was not asked to actually supervise Ms Lazarus in relation to any clinical research trials using the Medex device nor any studies that she may have conducted through the

University of Sydney and he never did so. He will give evidence to the effect that he has never seen or analysed any clinical trial data gathered by Ms Lazarus on patients tested with the Medex device whether at the Royal North Shore Hospital or the Kolling Institute of Medical Research. He did not provide Ms Lazarus with any of his patient lists nor did he, nor did she ever request access to them. Indeed, the evidence will establish that Ms Lazarus did not examine a single patient of Professor Smith with the Medex device.

10 The inquiry will also hear evidence that the person who claimed to be Michelle Lazarus approached Professor Gil Burton, the head of the Department of Obstetrics and Gynaecology at the Royal North Shore Hospital at about mid 2008 seeking an opportunity to conduct a clinical trial in relation to cervical cancer using the Medex device. The Department of Obstetrics and Gynaecology does undertake clinical research trails from time to time. Professor Burton requested Michelle to provide a further, for a pilot study that was subsequently provided a month or so later.

20 He understood from what Michelle had told him, that funding for any clinical research trial would be from the Medex company once approval had been obtained from the hospitals Human Research Ethics Committee and thus, completely external of the hospital.

His receipt of the proposal led Professor Burton to have Michelle meet with Dr Sue Valdermere who worked at the Gynaecology Oncology clinic at the hospital to get the pilot study together so as to determine whether the Medex device might actually work.

30 A pilot typically involves eight to ten patients and the proposal was to examine patients who have had a pap smear screening test which had resulted in abnormal cells. The Medex device would then be used on these patients to see if a similar finding to the earlier screening was obtained. There was a discussion between Dr Valdermere and Michelle during which Dr Valdermere indicated that she could make patients with pre-invasive, and invasive cervical cancer available for the trial. After that discussion however, Dr Valdermere did not see Michelle again.

40 Professor Burton never saw a patient that had tested with the Medex device and never saw any results from any pilot study of patients examined with the device.

The evidence will indicate that an application for access to the Northern Sydney Central Coast computer network was also made on behalf of Michelle Lazarus on 22 October, 2008. The form relating to this purports to be authorised by Professor Burton. There is also a letter dated 6 May, 2009 apparently under the hand of Professor Burton and addressed to Medex Test Corporation in formerly Western Australia. The purports to report on the results of a “preliminary research trial” that evaluated the “usability of the

Medex test as a screening method in diagnosing for cervical cancer.” The authenticity of the letter is in question, particularly when it is considered that Professor Burton has never seen any results of any trial of the device whether preliminary or otherwise.

10 The inquiry will hear evidence that Professor Burton did not see Michelle again until about October, 2009 when a meeting occurred between them and the managing director of Medex Test Corporation Pty Limited and another gentleman from that company. There was then discussion about the Medex device and how it could be used in cervical cancer screening services. It was indicated that Medex Test Corporation was willing to fund the clinical trial. After this meeting, however, Professor Burton had no further involvement with Michelle or the Medex company again.

20 The evidence will also indicate that Ms Lazarus approached Dr Kenneth Vaux, the head of the Department of Urology at the Royal North Shore Hospital, initially by telephone in May, 2008 and again at a meeting in early 2009 and proposed a clinical trial of the Medex device to detect prostate cancer. At the meeting Dr Vaux appears to have signed a form after Ms Lazarus informed him that Professor Smith was to supervise her for her PhD studies and that he, Professor Smith was going to complete the blank form later. Despite a further appointment being arranged to discuss the proposal in more detail however, Dr Vaux had no further involvement Ms Lazarus.

30 There is a letter dated 12 June, 2009 on the letterhead of North Sydney Health which appears to have been signed by Dr Vaux and addressed to Inter Medical, also in Thornlie, Western Australia. The letter purports to report on the results of “clinical research” to assess the “ability of the Medex device to accurately diagnose symptomatic prostate cancer patients.” The authenticity of this letter is also in question. Dr Vaux was not involved in any such research.

Although a draft national ethics application form appears to have been prepared and purports to be an application for a study involving breast, cervical and prostate cancer using the Medex device, the evidence will show that no application for any approval was ever lodged for any proposed clinical trial at the Royal North Shore Hospital or the Kolling Institute of Medical Research nor was any approval ever obtained.

40 At the time the Royal North Shore Hospital formed part of the Northern Sydney Central Coast Area Health Service. The accounts payable procedure involved the use of a purchase order like the procedure at the Royal Hospital for Women or a non-order voucher. These vouchers required the signature of a requesting officer and an authorisation officer before payments can be processed. Further, similar vendor maintenance forms must be completed and submitted with respect to any new vendor. The evidence will show that the vendor maintenance forms relating to Medical and Clinical Informatics Consulting, the Ms Lazarus entity, and

Wish Consulting, the Michelle entity, were signed, dated and dispatched by a facsimile from Professor Smith's rooms on 22 October, 2009. Ms Lazarus signed each of these forms.

10 A signature that purports to be that of Professor Smith also appears on these forms. There is a question as to the authenticity of his signature on these forms. They were processed by the accounts payable section on 27 October, 2008. A further vendor maintenance form for Complete Health and
Medicine, that's the other Ms Lazarus entity, is signed by Ms Lazarus and
dated 21 October and purportedly signed by Professor Smith and dated the
same day. Again, there is a question about the authenticity of his signature,
particularly when it is considered that the Complete Health and Medicine
entity was not incorporated until 8 December, 2008.

20 As I have indicated, there was no ethics approval for any clinical trial using the Medex device at the Royal North Shore Hospital whether as a part of study or otherwise. The inquiry will hear evidence to the effect that not one patient was referred to Ms Lazarus by any of the medical practitioners approached by Ms Lazarus that I have referred to or any hospital staff
working in their respective areas of practice.

30 The evidence will show, however, that Ms Lazarus submitted a total of 40 invoices on behalf of the entities which she controlled and Wish Consulting which variously sought payment for goods and services provided for clinical research and marketing services. Each invoice was accompanied by a non-order voucher signed by Ms Lazarus as the requesting officer. A total of \$465,300 was paid out in respect of the 35 invoices that were submitted before anomalies were detected. Accordingly, no payment was made in relation to the last five invoices that were submitted. Of the 35
invoices that were paid, four were from Medical and Clinical Informatics Consulting for "goods and services or clinical research, examination tests" totalling \$66,000, nine invoices were from Wish Consulting for "clinical research, marketing services, cancer research" totalling \$89,100 and the remaining 22 invoices were from Complete Health and Medicine for "goods and services for clinical research, cervical cancer screening" totalling \$310,200.

40 A number of doctors at the Royal North Shore Hospital whose name and signature appeared on the non, on the non-order voucher forms as authorising officer will be called to give evidence before the inquiry. The authenticity of the signatures of most of the voucher forms is in issue. Four of the forms were signed by Dr Michael Back who was then Director of Radiation Oncology at the Royal North Shore Hospital and he did so on behalf of Dr Nick Pavlakis, the Director of Medical Oncology who was then on leave. It seems that Dr Back was approached by Ms Lazarus with an urgent request to sign the non-order voucher forms. She was wearing an official identification badge and she told Dr Back that she was a laboratory technician or the like and intimated to Dr Back that unless the forms were

signed there would be a hold up on the clinical trials continuing. Dr Back told Ms Lazarus that he did not hold any delegated financial authority to sign the forms but she was insistent and he obliged her request. One of the other doctors is unsure as to whether or not he also signed the forms.

10 Another aspect there bearing on the authenticity of the documentation is the fact that 15 of the invoices submitted on behalf of Complete Health and Medicine and purporting to relates to goods and services provided by that entity predate its date of incorporation. Further, there is no evidence to suggest that Wish Consulting provided any marketing services to the Royal North Shore Hospital or that any such marketing services were ever requested. Again, the payments appear to have been made on the assumption that the Royal North Shore Hospital had some contractual obligation to pay the invoices that had been submitted. The evidence will show that the goods and services were not requested or provided and that no contractual obligation existed to pay the invoices at any time.

20 Many of the payments that were made by each of the hospitals occurred during a transition phase where the accounts payable sections of the respective area health services were handed over to the Health Support Services and there was attrition of existing staff and the engagement of new staff or employment agency contractors. These events may go some way to explain why appropriate accounts payable procedures were overlooked and certain deficiencies in the system were capable of exploitation.

Commissioner, that concludes the remarks I wish to make in opening.

30 THE COMMISSIONER: Thank you, Mr Alexis. The Commission will adjourn for a short period.

SHORT ADJOURNMENT

[11.58am]

THE COMMISSIONER: Mr Alexis?

40 MR ALEXIS: Commissioner, we have prepared a folder entitled Examination Bundles, which endeavours to conveniently assemble in chronological order what might be described as the material documents the inquiry will be concerned with. I hasten to add it doesn't include every document. And I'd seek to tender that Examination Bundle. May I indicate there are two tabs in the bundle, each identifies the two hospitals that we are concerned with. Those tabs are intended to indicate conveniently the location of the relevant invoices which sit behind those tabs. They don't purport to indicate that all or the documents relating to that hospital reside behind those tabs, because chronologically, that's not how they work.

THE COMMISSIONER: Yes.

MR ALEXIS: So could I tender the Examination Bundle.

THE COMMISSIONER: Yes. The Examination Bundle will be Exhibit 1.

**#EXHIBIT 1 - BRIEF OF EVIDENCE CONTAINING COMPANY
INFORMATION AND INVOICES FROM ROYAL HOSPITAL FOR
WOMEN AND ROYAL NORTH SHORE HOSPITAL**

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MS FURNESS: Commissioner, might I just note that the application form to the ethics committee at the South Eastern Area Health Service isn't complete in the bundle, the copy that I have, and we can certainly make a complete version available if the Commission wishes to have it.

THE COMMISSIONER: Yes, thank you, Ms Furness. Perhaps you could make necessary arrangements with Mr Alexis about that.

20 MS FURNESS: Yes.

THE COMMISSIONER: Mr Alexis?

MR ALEXIS: Thank you, Commissioner. I now propose to call Sandra Lazarus to give evidence, but before I do I understand there is either an application or at least some matters that my learned friend here have for the Commission and perhaps that should occur before I call Ms Lazarus.

30 THE COMMISSIONER: Yes, very well. Yes, Ms Soars?

MS SOARS: Commissioner, I just wish to indicate that Ms Lazarus wishes to make a blanket claim in respect to self-incrimination privilege in respect to- - -

THE COMMISSIONER: Yes. I'll make a Section 38 order.

40 MS SOARS: As you please. And, Mr Commissioner, I'm also instructed that my client has a medical condition which may be relevant in terms of considering her evidence, and I have some medical reports that relate to that medical condition which I have already provided to my friend, my learned friend. And I seek leave to hand the copy up to you, Mr Commissioner, and just to identify that the medical condition to which it refers is, she has a, she had a cerebral lesion in the left region of her brain and I'm instructed, it's not expressly stated in the reports, but this has left to, led to left brain slowness and she has cognitive reading and speech- - -

THE COMMISSIONER: Well, if it's not in the report, how am I to deal with it?

MS SOARS: At least, Commissioner, you can take note of the fact that she did have this lesion and she had treatment for it.

THE COMMISSIONER: Well, I'm not a doctor. I don't understand what the consequences are. If you wish to draw attention to that or make submissions based on that, it would be necessary for you to provide the evidence to support it.

10 MS SOARS: As you please, Mr Commissioner. Perhaps I could seek to get another medical report and produce it later in- - -

THE COMMISSIONER: Yes. I'm not sure what the purpose is of this.

MS SOARS: Well- - -

THE COMMISSIONER: Is this, is this to, is this to found some submission on credibility in advice or- - -

20 MS SOARS: No.

THE COMMISSIONER: What is it?

MS SOARS: No, Commissioner, just in relation to some assessments you may have to make in relation to demeanour and credibility and- - -

THE COMMISSIONER: Well, that's what I mean.

MS SOARS: Yes.

30 THE COMMISSIONER: You are certainly at liberty to provide whatever evidence in that regard you wish.

MS SOARS: Thank you.

THE COMMISSIONER: But there has to be evidence.

MS SOARS: Yes, Commissioner. Thank you.

40 THE COMMISSIONER: Yes. Now, Mr Hogan, do you want to say something?

MR HOGAN: Not in relation to- - -

THE COMMISSIONER: You, no.

MR HOGAN: (not transcribable)

THE COMMISSIONER: Yes.

MR HOGAN: (not transcribable) Section 38.

THE COMMISSIONER: Yes, you did, yes.

MR HOGAN: And I don't think (not transcribable)

THE COMMISSIONER: Yes. Mr Alexis?

10

MR ALEXIS: Thank you, Commissioner. I call Sandra Lazarus.

THE COMMISSIONER: Yes, please be seated, Ms Lazarus. Pursuant to Section 38 of the Independent Commission Against Corruption Act, I declare that all answers given by Ms Sandra Lazarus and all documents and things produced by her during the course of her evidence at this public inquiry are to be regarded as having been given or produced on objection and accordingly there is no need for her to make objection in respect of any particular answer given or document or thing produced.

20

PURSUANT TO SECTION 38 OF THE INDEPENDENT COMMISSION AGAINST CORRUPTION ACT, I DECLARE THAT ALL ANSWERS GIVEN BY MS SANDRA LAZARUS AND ALL DOCUMENTS AND THINGS PRODUCED BY HER DURING THE COURSE OF HER EVIDENCE AT THIS PUBLIC INQUIRY ARE TO BE REGARDED AS HAVING BEEN GIVEN OR PRODUCED ON OBJECTION AND ACCORDINGLY THERE IS NO NEED FOR HER TO MAKE OBJECTION IN RESPECT OF ANY PARTICULAR ANSWER GIVEN OR DOCUMENT OR THING PRODUCED.

30

THE COMMISSIONER: Now, Ms Lazarus, do you wish to give your evidence under oath or do you wish to affirm the truth of your evidence?

MS LAZARUS: Under oath.

THE COMMISSIONER: Would you swear Ms Lazarus in.

40

THE COMMISSIONER: Mr Alexis?

MR ALEXIS: Madam, could you state your full name?---Sandra Synthia Lazarus.

What's your current address?---33 Pangari Crescent, Dharruk 2770.

10

Do you currently have an occupation?---Um, no.

Now, Ms Lazarus, can I start with some questions in relation to the corporate vehicles that were referred to in the opening. Firstly, the company, Medical and Clinical Informatics Pty Limited, is it the case that you're the director of that company?---Yes.

You are its sole shareholder?---Yes.

20

Does that company currently have any employees?---No.

In 2007, did that company have any employees?---No, but there was potential employment opportunity.

In 2008, did that company have any employees?---This is Medical and Clinical that you're talking about?

That's the company we're dealing with, Ms Lazarus?---Oh, okay. Um, yes.

30

Who was that employee?---Michelle Lazarus.

And did the company have any other employees?---No.

In the 2009 year did that company, Medical and Clinical Informatics, have any employees?---No.

40

Now, we will come to the invoices that were generated on behalf of that company to each of the two hospitals in a moment, but can I just, as a preliminary matter, ask you this. Did that company trade in its own right in 2008 and 2009 or was it the trustee of an underlying trust?---A trustee of an underlying trust.

What was the name of the trust?---Lazarus Family Trust.

Was it a discretionary trust?---I don't know what that means.

Do you know what type of trust it was?---I don't know. I'm sorry, I don't know what type of trust. I don't understand, like.

Now, were there any beneficiaries of that trust?---Yes.

Who were they?---Myself, my mother and I think that's it, from the top of my head.

10 All right. So you and your mother were the beneficiaries. And may we take it that as the sole director of the trustee company, you were the one that made decisions about the distribution of income to the beneficiaries of that trust. Is that right?---That's correct.

Thank you. Now, can I come to another company known as Complete Health and Medicine Pty Limited?---Yes.

You're the director of that company?---Yes.

You're the sole shareholder of that company?---Yes.

20 Does it have any employees?---No.

Has it ever had any employees?---Yes.

Who and when?---In 2009 for a short while I had my mother looking at a few documents for me.

And when did her term of employment commence in the 2009 year?---I wouldn't be able to tell you the exact date.

30 Approximately?---Early 2009.

And when did her term of employment come to an end?---Well technically it hasn't.

Was she paid at all for her services as an employee during that time?---No. No.

She was a voluntary employee was she?---That's correct.

40 All right. Now did that company trade in its own right, in the sense that there was no underlying trust?---Ah, yes.

Thank you. Now you mentioned a moment ago your mother, is her Christian name Helen?---That's correct.

And does she go by the name Dr Helen Elias?---Yes, that's her maiden name.

Thank you. Now was she ever appointed the managing director of Complete Health and Medicine?---Yes.

When was that?---Early January.

Which year?---2009.

And for how long has she served in that capacity?---Oh, she still is on a voluntary basis.

10

All right. May the Commission take it that as the sole director and shareholder of that company, she is under your absolute control and direction in terms of her work as managing director?---That's correct.

And I finally come to the company Wish Consulting Pty Limited. Now is it your understanding that that's a company of which your sister, Michelle is both the director and sole shareholder of?---Yes. Sorry, I can't hear you very well.

20 I'll try and speak up?---Sorry.

If ever you can't hear me, Ms Lazarus, can you let me know and - - -?
---Yes.

- - - I'll try and remedy it immediately?---Sorry.

Now you understand that an issue in this inquiry are invoices that have been prepared by Wish Consulting and sent to each of the two hospitals?---That's correct.

30

Now I'll come to the detail, I can assure you, but in relation to the invoices that are in question, were they generally prepared by you or by your sister, Michelle or both of you?---For Wish Consulting?

Yes?---In collaboration, yes, together.

All right. And in relation to each of the invoices the details of which we'll come to, were they prepared in relation to the work that was performed by Wish Consulting for each of the hospitals?---Yes.

40

And may the Commission take it that in so far as the dispatch of those invoices to the hospitals is concerned, Michelle, your sister was well aware of the steps that you were taking to submit them to the hospital and procure a payment of them?---Sorry, can you be a little more clear? What do you mean, like - - -

Just your sister was aware that you were sending the invoices that had been prepared in collaboration to the hospitals?---Yes, to the hospital for payment, yes.

And as you understood it when the invoices were paid she was happy about it?---Yes.

All right?---Well she, she was aware of it, so she was happy.

10 Now Ms Lazarus, we've prepared as you would have just heard a bundle of examination documents - - -?---Ah hmm.

- - - as being described as Exhibit 1?---Yes.

Could I show you that bundle, please?---Yes.

Okay. You will see when you open the bundle that there are page numbers in the top right hand corner. Do you see that?---Yes.

20 Now is it the case that you've already had an opportunity to go through this bundle with the assistance of your lawyers?---With Julie, yes, with my - - -

So you got this bundle I think last week and you've had a chance to go through it have you?---Yes.

All right. Now could we start please at page 5. And should we understand the document at page 5 to be a printout from the website of the Australian New Zealand Clinical Trials Registry?---Yes, that's correct.

30 And should we understand that by the entry dates submitted and the date 6 January, 2008 that that is the date upon which the registration details for the proposed clinical trial referred to in the document were provided to that registry - - -?---Yes.

- - - and provided by you?---Yes.

Now we see if one looks at the third page of the document or page 7 of the examination bundle, reference to the Royal Hospital for Women?---Yes.

40 And then on page 8 of the document we see Professor Neville Packer referred to as the contact person for scientific queries. Do you see that?---Yes, that's correct.

If you just come back to the front page of the document on page 5 of the bundle and if I can just ask you this question: by the time the registration details have been submitted to the registry by you - - -?---Ah hmm.

- - - had you spoken to Professor Hacker at the Royal Hospital for Women about the idea of conducting a clinical trial at that hospital?---Yes.

And if we perhaps use the date 6 January, 2008 as a point of reference when prior to that did you have the first discussion with Professor Hacker about that subject?---In late 2007 there was email correspondence of a protocol for the pilot and the protocol for the trial going back and forth between Professor Neville Hacker and I for his approval and that's in late 2007.

10 Right. And in the course of those discussions was there any particular discussion about the conduct of a pilot trial?---Yes, that's correct.

And should we understand a pilot trial is something like a preliminary trial where you do a test on a limited number of patients - - -?---Yes.

- - - to see whether a more fulsome trial is worthwhile?---Yes, that's correct.

And did Professor Hacker say to you that a pilot of about ten patients would be an appropriate pilot trial in this instance?---Yes, that's correct.

20

All right. And did you have discussions about how the pilot trial and any future clinical trial would be funded?---Yes, that's correct.

And can you tell me what the discussion was concerning the subject of funding?---We had a discussion in regards to the funding and that there would be an external sponsor company. This company would be Sydvat. Prior to that there were discussions with the CEO of Medex and Sydvat. He is the same person, Johel Neiron. Prior to that he provided funds for the, the trial at Strathfield and he provided the funds for St Vincent's Hospital as well.

30

Just coming back to Professor Hacker if I may?---Yes.

Would it be correct for the Commission to understand that your discussions with Professor Hacker in late 2007 before the proposed trial was registered - - -?---That's correct.

- - - was on the basis that any costs associated with any trial, being it a pilot or - - -?---Yeah.

40

- - - or larger scale trial - - -?---Ah hmm.

- - - would come from sources completely external at the hospital?---Yes, that's correct.

All right. Now, did you also discuss the subject of ethical approval - - -?
---Can I get a pen?

I'm sorry, Ms Lazarus?---May I have a pen?

We will oblige if we can?---Thank you.

With the Commissioner's permission of course. Are you intending to mark the bundle of documents that's in front of you?---Shall I not?

Well, I would prefer that you didn't - - -?---Okay.

10 - - - because other witnesses might need to use it?---Okay, sorry, I thought it was my copy.

If you want to make a mark on something else would you let me know?
---Oh, yes, sorry, I thought this was my copy.

All right, we might proceed. I think I was coming to the subject of ethical approval and - - -?---Yes.

20 - - - in the period of late 2007 - - -?---Mmm.

- - - what was discussed between you and Professor Hacker on that subject?
---Sorry, late 2007?

30 Yes?---I was to begin working on a protocol for both the pilot study and the larger study for there'd be only small alterations. This protocol was approved in personal meetings and via email as well which we, which there are copies of, by Professor Hacker and once he had approved the protocol he asked me to start collaborating background information as part of the requirements in ethics application, not really a complete literature review but background information regarding conventional testing which is used to diagnose cervical cancer and cervical problems.

So Ms Lazarus, is this, is this the position, that from the discussions with Professor Hacker in late 2007 you understood that the pilot trial - - -?---Ah
hmm.

- - - and indeed any larger scale trial - - -?---Yes.

40 - - - could not proceed without ethical approval?---No, that's not correct.

Well tell me what your understanding was in late 2007, please?---My understanding was that the pilot will, will begin before an ethics application is even put in.

Right. Just, just stop there if you would?---Yes.

Could you tell me please how it was that you came by that understanding, that is that the pilot study could proceed without approval?---This, my

understanding, well I became aware of this when I conducted a trial at Strathfield Private Hospital where the ethics application was being processed and I had the permission from the supervisors to be conducting tests and screening patients before ethics approval was even received. And that's evident from the patient files that you obtained, the ICAC obtained from my residence for the 200 patients that were screened in breast. If you look at the date, the approved date, the approval for the clinical ethics approval, and this was in the presence of both the doctors, Professor Gilette, David Gilette and Professor Hugh Carmalt who have authorised and signed every single report and also Ethics Committees contact Professors directly without my knowledge in writing. My name does not appear on any letter as to the outcome and the status of the ethics application. I was not even once contacted as just being the researcher via written or verbally by the Ethics Committee. Every correspondence written between Ethics Committee and the principal investigator, which is the supervising professor is done and written directly to them. And if they wish to show me a letter they will show me a letter.

Ms Lazarus - - -?---Yes.

20

- - - I'd be grateful if you could attend as directly as you can to my question?---Oh, sorry.

And we'll get through the examination process - - -?---Okay.

- - - for more efficiently?---Okay.

If you want to expand on something please let me know?---Okay.

Ms Lazarus, should we understand from the evidence that you've just given - - -?---Ah hmm.

30

- - - that the understanding that you had in late 2007 - - -?---Ah hmm.

- - - concerning the performance of a pilot study - - -?---Yes.

- - - in advance of or without ethical approval - - -?---Ah hmm.

- - - came from some experience that you'd had from Strathfield Private Hospital?---That's correct.

40

So should we understand that the process of conducting a pilot study - - -? ---Ah hmm.

- - -without ethical approval was not something that you understood was from Professor Hacker?---It was because he knew when I was developing the ethics application, again constant communication, and he introduced me

to the staff members and he at no point told me that I was not to screen any patients prior to ethics approval for the pilot study.

All right. Now could I ask you to go please to, pardon me, page 7 of the examination bundle. We still are in the registry document. And do you see about half way down that page there is a reference to the funding source and adjacent to that reference is a reference to the Royal Hospital for Women. Do you see that?---Yes, that's correct.

- 10 Now in late 2007 you told us that your understanding based on your discussions with Professor Hacker was that funding would be external. Did something changed between those discussions and the time you submitted this form to the registry?---No, no, there hadn't.

Can you explain please why then the funding source on this document is referred to as the hospital?---I hadn't had the details, the letterhead or anything like that from the funding body. And in terms of sponsor I should have left it blank and said none, but nevertheless I have written the hospital.

- 20 All right. Now if you come down the page you'll see the words in bold script, Has the study received approval from at least one Ethics Committee? Do you see that?---Yes.

Now you accept that you responded to that question in the affirmative as we see it there?---Yes, that's correct. And that's in conjunction with ethics approval from the Concord Research Ethics Committee.

- 30 So should the Commission understand then that your answer to that particular question about ethical approval was based on the experience that you've told us about at Strathfield and not the result of anything that Professor Hacker told you about this particular proposed study?---No, that's correct. It's, here it says any one committee in regards to the clinical study and there was approval, full complete approval from the Concord Ethics Committee for the Medex research trial. So based on that I've said yes.

- 40 Should we understand that when you answered that question in the affirmative you were well aware as a fact that no application let alone approval had been given for any study at the Royal Hospital for Women? ---That's correct because I was the one developing the ethics application in collaboration with Professor Hacker.

So what should we understand then that when you answered the question, Has this study received approval? You were expecting that approval would be given because it hadn't been given at that stage had it?---Yes, that's correct. I was - - -

So this was responded in anticipation of approval wasn't it?---No, not really.

Well how was it (not transcribable)?---It was in response to that, Has the study received approval? For breast cancer it had received approval, for cervical cancer it hadn't. I see what you're saying, it should say no - - -

Mmm?--- - - - for this institution, but in terms of study receiving any approval from one ethics committee, that would be yes.

10 Page 10 of the examination bundle Exhibit 1 is a printout from the World Health Organisation, a registry, a form for International Clinical Trials. Is that right?---That's correct.

And again were you the source of the information that we see set out in relation to the proposed trial referred to there?---Yes, that's correct.

And was this information provided independently of the earlier registry that I took you to or is the information here - - -?---It's, I think the programme copies it through.

20 So I was just going to ask you whether or not the information here is populated, I think is the expression, from the information contained in - - -?--Yeah, I think it's just populated.

- - - the ANZ CTR website?---I think it's just populated that way.

All right. Now can I then bring you to the documents at page 12 and following through to page 24 and you see those as copies of applications and documents with respect to your prospective employment at the Royal Hospital for Women?---Yes, that's correct.

30 Now the handwriting on page 12 is that your own?---That's correct.

And similarly on page 13?---Yes.

Is that your signature we see in the bottom right hand corner of page 13?---Yes.

And similarly your writing and signature on page 14?---Yes.

40 I was referring to the handwriting?---Okay.

And on page 15?---Yes.

Similarly on 16?---Yes.

And on page 18 is that your name, signature and date with respect to your declaration?---Yes.

And on page 19 is that your handwriting and signature at the foot of the page?---Yes.

And this related to a criminal record check?---Yes.

And could I ask you with respect to the description of position title and job title, do you see that about half way down the page?---Page 19?

10 Page 19. Do you have that?---Ah hmm. Yes.

And you appear to have written the words principle, P-R-I-N-C-I-P-L-E hospital/clinical researcher?---Yes.

How should we understand you came to write those words on this form at the time that you did in relation to the prospective employment or position at the hospital?---That's the position I held at Strathfield. The exact title was the principle hospital scientific researcher. I've written principle hospital clinical researcher, but those words are exactly the same as the words that were used by the New South Wales Employment Description.
20

You may have misunderstood my question, Ms Lazarus?---Sorry. How did I come about to put those words? Yeah, that's what I'm explaining.

Who, who told you that it was the position or the title that you would be obtaining at the hospital when you completed these forms?---Professor, Professor Neville Hacker.

So - - -?---That was in accordance to what was outlined by the New South Wales Health Department as to the description and payment details for each person that's involved in clinical trials so it's, it's a generic thing so it's not that someone came up with it or he came up with it or I came up with it. It's exactly what's outlined.
30

Now, you've told us about the discussions you had with Professor Hacker in late - - -?---Ah hmm.

- - - 2007?---Yes.

40 May we take it that discussions with him continued up until at least the time that you signed these series of forms that I'm taking you through?---Oh, yes.

And was there any change in your understanding about the funding of the clinical trials, that is to say that any cost would be covered by an external sponsor?---Yes, always the costs would be covered by an external sponsor.

So your understanding never changed?---No.

And was it in the course of those discussions that he told you that your position title or job title would be that as we see on page 19 of this form?
---Yes, that's correct.

So the - - -?---That's for the, the grade of payment that goes with it as well.

So the description of that position - - -?---Ah hmm.

10 - - - is one that came from him and no one else. Is that your evidence?
---This description came from the New South Wales website and those words appear exactly the same so it's not, like I say, it's not something that he made up or I made up, they appear exactly to that, it's a job description.

You were being supervised as you understood it by Professor Hacker?
---That's correct, yes.

He was the one that set out the range of positions you could ever hold at the hospital, the one that we see on page 19 - - -?---That's right.

20 - - - was going to be yours, is that right?---That's correct.

So the source of that - - -?---Yes.

- - - whether it may be referenced generally on the website - - -?---Oh, okay, yes, I didn't understand.

- - - came from Professor Hacker?---Oh, okay.

30 Is that your position or not?---Yes, that's correct.

Thank you. Did you also complete and sign what we see on page 20?
That's one of your - - -?---Just my name.

Thank you. Similarly we see your name and signature on page 21?---Yes.

22?---Yes.

40 And name and signature and date on page 23, is that right?---Yes, that's correct.

And we see photocopies of various cards that were provided as part of your identification - - -?---That's correct.

- - - vetting process. Is that right?---Yes, that's correct.

Now, could I then bring you through please to page 26 of the examination bundle?---Yes.

And do we see a letter to the ethics committee for the Royal Hospital for Women under cover of which the relevant ethics application and site assessment forms were submitted?---Yes, that's correct.

Now, did you prepare this letter?---Yes, that's correct.

And how should we understand the handwritten reference next to the date of the letter, namely the reference 0-8-/0-4-9 came to be placed on this letter?
---I don't know.

10

Do you see the word "governance" - - -?---Ah hmm.

- - - in handwriting next to the - - -?---Ah hmm.

- - - next to the reference S-S-A-4?---Yes.

Is that your writing?---No, that's not my writing.

20

And now we see Professor Hacker's signature on this letter, do we?---Yes, that's correct.

Do you recognise that as his signature?---Yes, that's correct.

And should we understand that this is a letter that you prepared, you typed?
---I drafted the letter, yes.

And you print it, is that - - -?---Yes.

30

In fact, you did everything with respect to the letter apart from sign it, is that right?---That's correct. The letterhead was obtained from the receptionist. She has access to letterheads and printing out so I gave her the information on a USB and she printed this out. Professor Hacker looked it, it outlines what are the attachments that will be delivered with the ethics application. For example, previous approval from ethics committees, details about the, the Medex device, related publications, patient consent form, research protocols, other internal reports, the site specific applications with the ethics application.

40

Now when you refer as you did in that answer to the receptionist, to whom are we speaking of?---Helen.

That's Helen McGilligan?---I don't know her last name.

All right. You understood her as Mr, I withdraw that I'm sorry. You understood her as Professor Hacker's personal assistant?---Yes, that's correct.

All right. Now, is, is your evidence that you provided the form of this letter on a USB and - - -?---That's correct, because she printed out Professor Hacker's and Professor Donald Marsden's CVs for me as well which were the requirements for this, for the submission of the ethics application.

And did you have access to the letter for the Gynaecological Cancer Centre?
---Yes, for the patient consent forms, yes.

10 So in relation to the preparation of this letter your evidence is that it was Helen who printed the letter in the form that we see before Dr Hacker signed it. Is that right?---Yes, and the patient consent form, the first ones, the ones that I handed with this application were all printed at the same time including the patient, sorry, not patient, the professors' CVs as well, after which I had access to.

But I take it you also were able to obtain access to the letterhead of the Gynaecological Cancer Centre for the hospital if you needed?---Oh, they were in a tray on a table on, they're there, yes.

20 All right. Now - - -?---Because each form, patient consent form which is eight pages long needs to be printed on a letterhead.

When you tell us that you saw Professor Hacker look at the letter - - -?---Ah
hmm.

- - - may we take it that you observed him looking at the letter?---Yes, it was in his office.

30 And did you observe him holding his pen in his hand and signing the letter?
---Yes.

Are you sure about that?---A hundred per cent.

All right. Now, we then turn if we may to the form of national ethics application form which commences at page 28 and just to make it clear for everyone concludes at page 76 of the examination bundle, is that right?
---Yes.

40 Can I take you to some particular parts of it?---Yes.

Firstly if I may, on page 32 of that form, I'm sorry, I withdraw that, I'm sorry, if we come back to page 31?---Okay.

We have some personal detail concerning yourself as the applicant. Do you see that?---Yes.

And the Commission can take it that you were the one that completed this application form?---Yes, that's correct.

And was it completed on line?---Yes.

In other words, the typing that we see within the standard format - - -?
---Yes.

- - - was information that you - - -?---I populated.

- - - populated into the form, is that right?---That's correct.

10

And was it lodged with the ethics committee electronically? That is to say, it was sent once the form had been completed?---No, no, no.

I don't mean only electronically?---No, I don't know, I don't understand what you mean by - - -

I can put the question again. Once you completed the form did you submit the form having completed it to the committee - - -?---Electronically, like - - -

20

- - - electronically?---No, no.

So did you then print it out?---The form, once you put it online you have to say submit, whether the programme submitted it to them or not I'm not aware of but it gives me a number, a registration number after which I cannot make any changes to the application once that number has been issued. If I am to make any changes I would need to start a new application so it becomes read only and no changes can be made at which point I printed out this application, again, in constant communication with
30 Professor Hacker just in case I do make an error and I, because like I said, you can't go back and make changes so this application prior to being submitted or locked as the website outlines that the application is now locked and can't, no change, further changes can be made was approved by Professor Hacker. Draft copies of this were printed out and given to him to review.

Before you pressed the submit button?---Before, before I pressed the, yes, lock form submit button.

40

All right. So can I just try and capture some threads of what you've just said, Ms Lazarus?---Yes.

Firstly, we should understand that the content of this application form- - -?
---Yes.

- - -is your work?---Yes, that's correct (not transcribable)

Secondly we should understand that before the form was submitted to the Ethics Approval Committee- - -?---Ah hmm.

- - -it was provided to Professor Hacker for his review and approval?
---Yes, that's correct.

And I gather his signature?---No.

10 All right. Well, I'll come to that. If I could ask you to go to page 31 where I think I was a moment ago?---Yes.

And we see there some personal details concerning yourself. Is that right?
---That's correct.

And if we turn over the page, page 32 of the Examination Bundle or page 5 of the application- - -?---Ah hmm.

20 - - -we have some detail concerning your qualifications, expertise and prior experience. Do we see that?---That's correct.

And do you see the reference under qualifications to a PhD and the word in brackets, "Current?"---That's correct.

30 Now, at the time this was prepared, were you enrolled in a PhD course with any university?---Um, steps were being made um, to re-enrol. I was enrolled in 2003. Um, I'd um, deferred ah, in year, I can't remember now, sorry, can't recall. Nevertheless I was um, currently not ah, enrolled in a PhD with the University of Sydney but all applications and supervisor changes had been submitted already and (not transcribable) PhD and change of supervisors applications had all been submitted.

Do you recall what I said about attending directly to my questions?---Sorry.

Perhaps you didn't understand it though. At the time you prepared this application, were you currently enrolled as a PhD student with any university?---No.

40 So should the Commission understand that the reference to current was really in truth a statement which indicated your expectation that you would re-enrol in that course at some future time?---Ah, it was actually a day or two after. So it wasn't like in the next month or so, it was around exactly the same time, the originals which you have already obtained of my re-enrolment.

That's fine. Now, pardon me. Could I also ask you to come through to page 35 of the application?---Yes.

And do you see that there's reference to a start date responding to question number 4 on that page?---Yes, that's correct.

And was it your expectation at the time you prepared this application in April 2008 that the study was likely to start in May?---Um, this date was actually discussed with Professor Hacker because I was, well, I was unsure as to what date that I have to put in there.

10 Mmm?---And he said the applications usually take a month, a month and a half, so I should allow that time, and that's the date he's provided and that's the date he said, well, put one year from now.

Right. And if we could turn now to page 37 and I wish to direct your attention to the question at the foot of that page, will consent be sought from the patient, from participants- - -?---Yes.

- - -for the collection and use of information about them. And not surprisingly I suppose- - -?---Yes.

20 - - -you've answered that, yes?---Yes.

And then if we come over the page, there's a question about the collection of information. Do you see that?---Which question, sorry?

15?---15. Yes.

And it's, and you've responded by saying the information will be, collected will be used to diagnose- - -?---Patient conditions.

30 - - -the participants' medical condition?---Ah hmm.

The collected information will be compared to the participants' medical history and so on. Do you see that?---Yes, that's correct.

And then with respect to that information, do you see the question in 18 which asks in what format the information will be stored? Do you see that? ---Yes.

40 And you've responded by referring to paper copy computer files and CD. Do you see that?---Yes, that's correct.

And do you see in 19 there's a particular question about measures to be taken to ensure security of the information and you've responded in the way that we see, I take it, the data is to be backed up on CDs which- - -?---Yes.

- - -are stored in accordance with the Ethics Storage Policy- - -?---That's correct.

- - -and the other material referred to. Do you see that?---That's correct.

And may we take it that when you had completed this application you had an understanding of what storage of information in accordance with the Ethics Storage Policy was?---Um, that all um- - -

Sorry, do you answer my question as yes, you did have an understanding?
---A rough understanding, outline, yes.

10 Well, tell me what that rough understanding was at the time?---Okay. That was that um, all um, paper needs to be stored in a filing, the filing area of the hospital or the research institution and um, all patient um, patients cannot be identified directly um, that a coding, a code has to be used. Um, and that all sensitive information needs to be um, stored in a secure area.

So we should understand, Ms Lazarus, that at the ethics application stage you had a very clear understanding that the information to be obtained from a patient- - -?---Yes, was sensitive.

20 - - -was to be tested as part of the trial?---Sorry?

The information that you obtained from the patient that was to be tested as part of the trial was to be retained not only in a hard paper copy but also backed up on a computer file and on a compact disc?---No.

Well, isn't that what you were saying at page 38 of the application?
---Um, that's because of that program that we were using. It depends what research it is. Most research just contains paper information. All, all information will be paper unless in this case, because it was a computer
30 application um, that's the only reason why the information was on a computer or in soft form. Like most, 99 per cent of the time, all research is on hard copies like paper.

All right. So should we understand that- - -?---That's 'cause in relations of the- - -

- - -at the application stage- - -?---Yes.

- - -you were proposing to retain a hard copy of the patient information- - -?
40 ---Yes.

- - -as well as a computer copy?---No, not patient information, only the Medex test results.

I see what you're saying. Thank you?---Yep. So- - -

So we could understand that in terms of- - -?---Yes.

-- a hard copy and soft copy, that related to the results of the testing only?
---Only, yes. Not patient information.

All right. And when the information was received into the computer-- --?
---Yes.

-- as a result of the test-- --?---Yes.

10 -- was that information then to be backed up on a compact disc independently of the laptop computer being used?---Um, yes, but that was only to be carried out once the full 200 patients were completed.

What, not after each day or each week or each month?---Not after each day, no. That was never done.

I see. All right. Now, pardon me. If we look on page 39, question 23 seeks to understand for how long the information will be stored. And you responded by referring to the period of 5 years after the last publication-- --?
---That's correct.

20

-- for the trial result?---Yes. That's standard with the Ethics guidelines.

30 And what does the standard, as you understand it, involve in terms of the retention for five years of both hard copy and soft copy?---Um, publication, whenever that comes out. I'm not quite sure in terms of if the, if you publish, if you've conducted a trial ten years ago and you publish a paper now, does that information still remain, do you start counting five years from ten years later when the last publication is published. I'm not quite sure in that terms, but this is the exact wording in terms of how long the information should be retained.

Leaving aside (not transcribable)-- --?---Yes, sorry.

-- purposes precisely when the five-year period commences-- --?---Yes.

-- do you have an understanding that both the hard and soft copy of the information from the testing results-- --?---Yes.

40

-- had to be retained for five years?---Yes, that's correct.

All right. And in response to question 24 you seem to have referred to the information from the project or trial being stored at St Vincent's Hospital. Was that a mistake?---That's an error.

Yeah. And was that because you used this form, I withdraw that, I'm sorry. Is that because the original form of this was sourced from the application you'd made at St Vincent's and you were making-- --?---Well, the first application was made to Concord, which would be Strathfield Private, but it

seems like when I was writing um, that information was just populated by copy and paste, so that should say Royal Women's. So just an error, typing error, that apparently no one picked up.

Now, if I could try and complete this document as- - -?---Ah hmm.

- - -quickly as I can before- - -?---Yes.

10 - - -before moving onto other things. On page 46 some detail concerning the enrolment of patients is provided and we see there a reference to 210 female patients, 10- - -?---That's correct.

- - -being for the pilot study?---Yes, that's correct.

And is that should we understand - - -?---Consistent with the discussions we had with Neville Hacker - - -

20 The word I was going to use Ms Lazarus was - - -?---Sorry, I didn't meant to - - -

- - -was discussion – reflective of the discussion you had with Professor Hacker concerning an initial pilot of ten.---That's correct.

And we should also in that respect see what you've said on page 50 of the application and - - -?---Page sorry?

Page 50 of the application according to the examination bundle pagination. ---That's correct.

30 And we see the two groups proposed, the initial group 1 being for 10, the pilot study. Is that right?---That's correct.

And then subject to that a further larger study thereafter?---That's correct.

Now just one or two final things about this application. Firstly, at page 48 if you have that. You see towards the top of the page there's a number 9 and then the heading, "Regulatory Committees and Ethical Considerations," Do you see that?---Yes, that's correct, yes.

40 And do you see that there is there written the final study protocol including the final version of the patient information sheet and consent form will be approved by the hospitals Human Ethics Committee before enrolment of any patient into the study. Do you see that?---That's correct.

Are they your words or are they standard words?---They're standard words.

But you adopted them?---Yes, that's correct.

Because you understood – didn't you – that ethical approval included - - -?
---Patient consent.

- - -the form of consent to be obtained from each patient before any test was undertaken?---That's correct.

And that an understanding that you had both in relation to the pilot study as well as any larger study?---Oh yes, that's correct and the patient and consent form and information sheet – sheets I should say, were developed and
10 submitted and outlined on that letter which is page 26, patient consent forms and each time a patient was recruited for the trial an 8 page form was given to them on letterhead, that's the standard patient consent form and information sheet must be on a letterhead that was provided to the patient during the recruitment process. The patient was allowed time to read the information sheet, well pages, there were actually 6 pages of information outlining what the trial's about, what the device is about, what we're trying to achieve, there were 6 pages, they read that. And the last two pages was the actual form written consent from the patient which they had to sign and
20 date.

All right. Thank you. Now you look at the bottom of page 48 of the examination bundle.---Yes.

There's a reference to the provision of the Medex device.---Yes.

And you see particularly the question has the sponsor or manufacturer agreed to supply the device free of charge for the duration of the trial, you've answered that in the affirmative.---Yes, that's correct.

30 So should we understand that at the time of completing the application you understood that the sponsor or the provider of the device was doing so free of charge.---That's correct, they did the same for Strathfield and St Vincent, for the test themselves.

And should we also look at page 54 of the application about half way down that page the box commencing with the number 2.---Yes.

We see the question, "will the project be supported in other ways, for
40 example in kind support, equipment by an external party e.g. sponsor", you've answered, "Yes," and again indicated that the device that is to say the Medex device would be provided free of charge on a loan basis. Can you see that?---That's correct.

Now both of those entries consistent with what we should understand your discussion with Professor Hacker was that we've discussed?---That's correct.

The equipment would be provided at no cost to the hospital?---That's correct.

Did that understanding ever change?---No.

So the Commission should understand that after the application was submitted your understanding always was with respect to the Royal Hospital for Women that the equipment, whatever that equipment was - - -?---Yes.

10 - - -that was provided was at no cost to the hospital?---That's correct.

Thank you. I should also draw attention to what appears at the top of page 54 of the examination bundle with respect to funding. Do you see that? ---Yes.

And in a similar way, is it the case that at the time you prepared the application your understanding was that 100% of funding would come from external sources – do you see the reference to other?---Yes, that's correct.

20 And you've bulleted the confirmed button. Do you see that?---That's correct.

And then you identify in the box there under the name of the funding provider as the University PHD Scholarship. Do you see that?---That was for the scholarship that I would be, the application that I put in for my scholarship for when I would be re-enrolled into the PHD.

All right so - - -?---That was in reference to that.

30 So what you had in mind when completing that part of the application form in the way that you did was that you were hoping to be received again by the University of Sydney as a PHD Student in the faculty of Medicine? ---That's correct.

40 How was that going to provide or give rise to any funds to cover the hospitals cost of any trial, is that - - -?---No, not the cost trial, the cost of the trial itself. That was still to be sponsored by Sydvat, we hadn't received a letter because the CEO of Medex of the Sydvat, they are two in one, said the application, ethics application copy had to be provided before he would be able to provide a letter confirming his, his, his support. That's why during sponsor on page, in number 1 where it says sponsor I've written "Not sort", because I hadn't received or rather Professor Neville Hacker hadn't received that letter of sponsorship as yet.

So we should understand that at the time you completed the application you did not have a sponsor for the trial at the Royal Hospital for Women?---Yes, that's correct in writing.

All right. You then when completing the first section of this page of the form in relation to “other”, you confirmed that that was the position, if you see on the right hand side there’s the words, percentage of project and you’ve - - -?---That’s correct.

- - -inserted there 100.---That’s correct, I should have written not sorted there as well.

10 But what you intended by completing the form in the way that you did Miss Lazarus was to indicate that the proposed clinical trial would be funded by some other source 100%.---That’s correct.

And when we look to identify to whom would be providing the funding, you responded in the next box, did you not, by referring to the University PhD Scholarship?---Yes, that was in relation to the scholarship.

20 All right.---So I’ve made, well not made an error, but my understanding would be I am answering in regards to the scholarship not in regards to the Medex sponsor for the trial itself.

Well, Miss Lazarus whether that be so or not, I won’t debate it now.---Okay.

Should we understand that you at no time understood that there would be any funding coming from any scholarship associated with any re-enrolment by you as a PhD student?---Sorry, sorry, can you repeat that question.

Certainly. We should understand that when you entered the words “University PhD Scholarship”- - -?---Yes.

30 - - -you were not expecting any funds to come from any scholarship associated with your re-enrolment as a PhD student with the University of Sydney to fund the clinical trial at Royal Women’s.---That’s correct.

All right.

40 THE COMMISSIONER: Can I just find out what the scholarship was, was there a scholarship?---There was an application for a scholarship that just it’s about \$200 I think a month, it’s just one of those little ones that you receive but it’s more to get, to be known to have received it rather than the funds they provide.

And did you apply for that scholarship?---Yes that’s correct, I did.

And when did you apply?---During the time of re-enrolment. All application forms there.

MR ALEXIS: Page 57 of the application contains provision for signature by you as applicant and principal researchers, do you see that?---Yes, that's correct.

And we should understand that your signature appears adjacent to the reference to your name.---Yes, that's correct.

10 And to the extent that you're able to say, does that appear to be your younger sister Jessica's signature adjacent to her name?---Yes, that's correct.

And at the time you completed this application what was proposed in terms of Jessica's role with respect to any trial that was to be conducted at the hospital?---Yep. Jessica at the time was enrolled in the University of, University of New South Wales in a medical science degree. She was hoping to get some experience, that's her area of expertise in terms of research. When this opportunity came forth I approached her, I said, you have some time as you are a part time student now, would you like to be a part of this clinical trial? Prior to this in 2007, Jessica had completed all
20 Medex training and was certified by the medical trainer for Medex who was Dr Itzhak Reitzfeld as well as the, the Medex CEO, Johel Neiron, she's fully certified and completed all training. Because she completed all those trainings, she was requested by Medex to present at the Australian Scientific Convention which was in October, 2007. Documentation that she's already provided in terms of registration of the conference and registration of completing the training as well. She had a lot of knowledge in the area. Because there were, because I, I was still writing reports and things like that I thought this would be a good idea or a good way for her to gain
30 experience. She was introduced to Professor Hacker as someone who'll be coming on board. He was very happy with her. They were sitting there talking about other unrelated things as well in terms of, because she was just at New South Wales, yeah, New South Wales, Sydney Uni of New South Wales, so there was a relationship, like there was communication there. I took her around, actually Professor Hacker did as well, he was, if I recall he was in his scrubs, so he went around taking Jessica around, showing her and he introduced her to Helen as well. At which point there was, we made our intentions known, like we would like, Jessica would like to be part of this trial. He gave her the okay. And then the following meeting he asked her to come back because he was in, I guess, not in a hurry but he spent quite a fair
40 bit of time with her, but he had the next appointment. Jessica returned to his office for the security clearance. He told her to go down and go get a security form and things like that. She went and did all of that. She filled it. It was all filled out. I helped her fill it all out. We returned to Professor Hacker's office, he signed it, authorised it and she had her badge. And it was all - - -

Just before, before you (not transcribable) application?---That's correct.

And I was hoping that you'd get to answer this, but what was proposed as her role? What was she - - -?---Just as a researcher.

What does that mean?---That means just like a general junior researcher there. She would conduct the test, because she knew how, she would compile these patient files, get information together during when she has time off through uni 'cause it's just walking distance.

10 So we should understand that at the time of the application you anticipated that Jessica would perform a role of actually engaging with patients - - -?
---Yes.

- - - obtaining consents - - -?---That's correct.

- - - performing the tests - - -?---Yes.

- - - obtaining the results?---That's correct. That's for that reason she had to go through all the security protocol.

20 And did you expect that she would be performing any other task?---No, that's about it.

And - - -?---Just maybe reviewing papers and stuff. But that's just background knowledge for her to get more understanding.

And in terms of remuneration for that work was it your expectation that her remuneration would be covered by funds provided by the external sponsors?---No, no, no.

30 Well was she to be remunerated for this work?---No. I told her I will give her some money because she's always asking money from her sisters. But we would, like I would support her in terms of, to get her to do a task for her pocket money rather or to money that she would ask for or money she wants to have, just I placed her in a position where she'll be actually doing something rather than just taking money off people in terms of money from sisters, basically. You know what I mean?

40 So we should understand that this, as between you and her was an informal arrangement, the benefit to her being that she will derive relevant important experience that she otherwise (not transcribable)?---The experience is important. That's correct. That's correct because she actually wrote, she enjoyed what she'd done and what she was doing so much that she'd for one of her, independently to this, had, had an assignment due for university and she actually ended up doing, completing an assignment successfully at the University of New South Wales in one of her subjects related to this clinical trial.

So as far as you were concerned her work, her attendance and her attention to the role that you describe - - -?---Ah hmm.

- - - was entirely voluntary and she was not to be remunerated for it?
---From, not from the hospital

But to the extent if she was to be remunerated that was more - - -?---An arrangement between the two sisters.

10 - - - a generous gratuity on your part. Is that right?---That's correct.

All right. Thank you?---As opposed to just giving her the money.

Now would you look at page 58 of the application?---Yes.

And you told us a while ago about the process of completing the form online and printing it off and providing - - -?---That's correct.

20 - - - it to Professor Hacker for his - - -?---Final approval.

- - - final approval. Did you attend upon Professor Hacker and see him sign the form adjacent to his printed name as we see it on the, on page 58?
---That's correct, signed and dated. This form page cannot be altered because of the serial numbers that the registration provides. So he needs to make, he made sure that each page was to his liking.

And should we understand that when you asked Professor Hacker to sign the application form and date it 11 April, 2008 - - -?---That's correct.

30 - - - he had before him the complete application?---Oh, yes, definitely. He has to.

Just so we're clear Ms Lazarus, he wasn't provided just with the page to sign?---No.

He was provided with the completed document?---Full complete document.

40 Thank you. What about at page 59, Associate Professor Marsden, we see that he appears to have signed this application form as a head of department on 16 April, 2008. Do you see that?---Yes, that's correct.

And again did you attend on Associate Professor Marsden and obtain - - -?
---For, for application, that's correct.

Just let me finish the question if you don't mind?---Sorry.

Did you attend on Associate Professor Marsden and observe him sign the application form as we see it at page 59?---That's correct.

And again was he provided with the whole application not just this page? Is that right?---Complete form.

All right?---Including the cover letter and attachments.

10 And did you observe at all both with Professor Hacker and Associate Professor Marsden whether they took time to peruse the application in some detail before they signed it?---Yes. That's because they also had the drafts from, the previous drafts that I had given them and they came back with amendments?---I see.

So did they take the time - - -?---To look at the final, yes.

I might ask the question if you don't mind, Ms Lazarus?---Sorry.

20 Did they take the time to check to see whether or not amendments that they had either suggested or proposed had been incorporated in the final draft to which they were signing?---Yes, that's correct.

And how long did the process take with Professor Hacker for him to peruse the document as amended from time to time in its final form before executing it?---The final copy, the full document was left with him, so he would have taken, well according to the signature he's taken a day.

30 But you told me a moment ago that you observed him both peruse and - - -? ---Yes, I went, yes, at a meeting. So I'd left this all with him and then had a meeting and then he signed it because he needed to discuss the application, what else is this and this and that. So he signed it in front of me.

But when you attended on Professor Hacker - - -?---Yes.

- - - for how long did you spend with him before you observed him sign the form and receive the signed form back from him?---Maybe ten minutes. In that meeting where he signed it, he just asked me general questions and he signed the form, he said, "Will you be submitting this today?" I said, "Yes, hopefully."

40 Where, where did this happen?---In his office.

At the hospital?---At the hospital.

Let me just clarify something with you, Ms Lazarus. How many times did you attend on Professor Hacker when he was seen by you to look at the application and sign it as we see it at page 58?---Do you mean the drafts as well or do you mean just this final copy?

The final one?---The final copy, once.

And what about with respect to Associate Professor Marsden at page 50, just the once?---Once to leave the copy with him and then to come back.

All right. And - - -?---At that stage Professor Hacker and my sister and I had already signed all the forms so when it got to Professor Marsden the form had all the signatures on it and it was left with him at his leisure to look at and come back to me.

10 And Professor Marsden's office is adjacent to Professor Hacker's is that right?---That's correct.

At the centre?---Yes.

And is that where you saw Professor Marsden too?---That's correct.

And saw him sign the form?---That's correct.

20 And how long did that process take with Professor Marsden?---Again just five, ten minutes, just, he asked general questions as well and, yeah, and signed and gave that back.

Now moving forward, at page 64 of the bundle you have, the second relevant application form relating to site specific, is that right?---That's correct.

And again this is a application that you prepared?---That's correct.

30 In the same way as the - - -?---This is exactly the, it's, it's a continuance, the ethics application, this is just a follow-on, it's, it's an application in one but just divided. Do you know what I mean?

The site specific assessment form has been completed in the same way as - - -?---Yes, that's correct.

- - - was done with the, the other form?---That's correct.

40 And at page 66 should we understand that either independently or from the earlier form the departments and services that were to be involved in the research were identified by you, the hospital and particularly the Gynaecological Cancer Centre, do you see that?---Sorry?

The bottom of page 66?---Yes, yes.

And then over the page 67 - - -?---Yes.

- - - with respect to the study budget - - -?---Ah hmm.

- - - did you complete the information the middle column concerning the sources of funding?---That's, that's correct.

And there you've referred to external funding coming from research funds, foundation/university (not transcribable)?---That's correct.

10 Did you anticipate when you completed this form that any funds would be provided from a university?---This form and this application get completed exactly the same time and they get populated from, this form gets populated automatically from the ethics application. That's what I was trying to explain. The took, the form was in one, it's just divided by just the title but the form itself is one so once you start populating the ethics application this form automatically gets populated, it's just like it's the next page.

But if the inputted information is not precisely the same - - - ?---Oh, yeah, that, that, that's - - -

20 - - - it may be (not transcribable) you must have inputted it independently? --- - - - been populated, yes, yes, yes, but I'm just saying in general it's the form in one.

Is what I just put to you correct or not?---What do you mean? Sorry.

If the information contained on this page of the form - - -?---Oh, this I've written myself.

- - - is not precisely replicated in the earlier form - - -?---Yes.

30 - - - it follows that you independently inputted that information, correct? ---Yes, that's correct, that's correct.

All right. Now in respect of the signature of Professor Hacker at page 70 of the examination bundle - - -

THE COMMISSIONER: Sorry, Mr Alexis, I don't understand this, 67 item 10 what has been set out next to "external funding."

MR ALEXIS: Thank you, Commissioner, let me go back to it.

40 Do you recall, Ms Lazarus, when I was examining you on the earlier application - - -?---Yes.

- - - we discussed your description of the source of funding being "university PhD scholarship"?---That's correct.

The Commissioner has drawn attention to what you've inputted as we see on page 67 of the site specific assessment form - - -?---Ah hmm.

- - - as external funding being derived from research funds foundation/university?---That's correct.

Now in relation to the reference to university - - -?---Ah hmm.

- - - should we understand that as - - -?---(not transcribable)

- - - a reference to the university scholarship to which you referred earlier?
---That's correct, you can, yes, its limited to what I can write, how many
10 words, characters I can put in there so it's a summary.

Well, it may be but in, well, is something missing from what we see in the printout?---No.

Should it say University of Sydney PhD scholarship?---Yes, yes, but I couldn't fit that in so I've just written University and the foundation referring to the research fund foundation referring to the Sydvat company so
- - -

20 Well, what is, what is a research funds foundation?---Just three words that I've tried to use to explain Sydvat's position and the university the words I've tried to use to explain the scholarship from the university.

So when you wrote the words "research funds foundation" you had Sydvat -
- -?---In mind.

- - - in mind, did you?---That's correct.

30 So why didn't we see a reference to that in the earlier form?---It should have contained it.

Was, did you have in mind at the time you completed this form any other foundation apart from Sydvat?---No.

All right.

THE COMMISSIONER: But the university wasn't really going to fund this, was it?---No, no, no, just the scholarship that I put through.

40 The scholarship was \$200 a month you said?---Yes, like I said, it's just mainly, mainly to be, to get that scholarship, that's the bigger part rather than the funds they provide.

Well, why did you mention the university then?---I did write university.

I know, I'm asking you why?---Why?

Yeah?---To refer to the scholarship.

That was going to provide external funding for these tests, was it?---Not for the tests, just for the scholarship.

Sorry, I don't understand?---Sorry, I don't understand what - - -

10 I'm trying to find out why you put the word "university" in as a source of external funding for these trials?---It's an external funding for, I guess it's a funding for the scholarship that I would get, not for the trial, not for the running of the trial.

So why did you put it in?---Because that's a source of funding.

For the trials?---For the trial I'll be conducting, for me to conduct the trial.

What, the university scholarship?---Yes. Not to conduct the trial, not to conduct the tests but for me to run the trial as part of my course.

20 MR ALEXIS: Is the position, Ms Lazarus, that when you completed each of these two forms that I've been taking you through you were acutely aware of the need to indicate that funding for any clinical trial would be external of the hospital?---That's correct.

In other words it was important for ethical consideration to ensure that the funding for any clinical trial was from a source external of the hospital at which the trial was conducted?---That's correct.

30 In other words, there had to be financial separation between those conducting the trial and those paying for the trial?---That's correct.

Otherwise the integrity of the results might come into question?---That's correct.

You understood all that, didn't you?---Yes.

Which is why when you completed the forms you wanted to make sure that the hospitals would not be funding any of the trial, is that right?---That's correct, they're not to fund the trial.

40 Now, I wanted to take you finally to page 70 of the site specific application form and do you recognise at the foot of that page under the heading "Declaration by the principal investigator" Professor's Hacker's signature? ---That's correct.

And should we understand that you attended upon him and observed him sign the site specific assessment form as we see at page 70 at the same time as him signing - - -?---Exactly the same time.

- - - the earlier application form?---That's correct. Like I said, it's in one application.

Thank you. And that occurred within the ten minute discussion - - -?
---That's correct.

- - - that you referred to a moment ago?---That's correct.

10 Yes, thank you. Now, could I just have you confirm the further employment related documents that we see from page 77 of the bundle is under, is under your hand, we see the privacy undertaking, is that your writing in relation to your name and your signature and your position?
---That's correct, yes.

And similarly on page 79, is that your handwriting that we see on that page together with your signature at the foot of the page?---Yes, that's correct.

20 Thank you. And similarly on page 82 is that your writing and signature and date?---That's correct.

Now page 83 I wish to draw attention to a letter that has been prepared, it seems to be signed by Professor Hacker and addressed to the Human Resource Department of the Royal Women's Hospital. Do you see that?---
That's correct.

Now should we understand that you are prepared this letter like you prepared the earlier letter which attached the ethics application?---No.

30 All right. Did you type this letter?---Yes.

So but when I asked you whether you'd prepared this letter, how should we understand your evidence if you typed the letter?---This letter was prepared with Professor Hacker because it related to my employment he needed to tell me what needed to go in the letter because I - - -

So when you say prepared with Professor Hacker should we understand that - - -?---He's in his office I'm at the - - -

40 Can I finish the question please.---Sorry.

Should we understand that he dictated it to you?---Roughly yes.

And so there was the discussion in his office was there?---That's correct.

At the Gynaecological Cancer Centre?---Yes.

And you were sitting, what – across the desk from him?---He has like a lounge in his office so I was literally right next to him.

Right. And did he - - -?---I took notes.

- - -tell you what the letter should say?---That's correct.

And you wrote that down?---I wrote that down on a piece of paper, I went outside because the three computers outside – no his – outside his room but still in the complex where the receptionist so it was right across the receptionist. I typed it out, printed it on a plain white piece of paper, took it
10 back to him. I said, "Is this what needs to be written?" He said, "Yes, that's fine address to," because I made an error in Vanessa's last name, spelling error, he corrected that. He said, "Can you fix that, there's an error in her last name." I went back, fixed it up, came back and says, "Is that better?" He goes, "Yes, print it off." I print it off and went back out, print it off in letterhead. Went back in, attached, he signed it, read it through signed it and I attached it with the rest of the application.

So in the process of him dictating the letter in effect to you, you preparing it on one of the computers that was available within the centre, you preparing
20 a draft. The only matter to which he took issue was the spelling of Mrs Madunic's surname. Is that right?---That's correct.

Apart from that, the letter was in a form that he was prepared to sign. Is that right?---That's correct.

He indicated that to you?---Yes, he said, "that's fine."

You then printed the letter on the letterhead of the Gynaecological Cancer Centre. Is that right?---That's correct.
30

And you then presented to him for signature?---That's correct.

And may we take it that this all occurred on the date the letter bares, namely the 17 of April, 2008.---That's correct, yes.

And is your evidence that you saw Professor Hacker sign the original letter after the steps we've just discussed had been worked through. Is that right?
---Yes.

40 Do you know what then happened to the letter after he signed it?---Yes, I attached it to the application that I filled out and I went to, keep going?

And did you do something - - -?---Oh, yeah, oh, sorry I thought you were going go ask a question.

- - - with the (not transcribable) application?---Yes, and that was delivered to Vanessa's office.

All right. You put it on her desk?---With the receptionist because - - -

Did you see Mrs Madunic about the letter and the attachments?---In a meeting several weeks later or days later, I'm not quite sure about the, the timeframe.

All right?---But there was a meeting.

10 Thank you. Now I wish to ask you some questions about the following document which commences at page 84 and finishes at page 91 being a letter and an attached letter of appointment from Wish Consulting. Do you see that?---Yes, that's correct.

Now can you tell me whether you had any involvement at all in the preparation of the letter dated 17 April, 2008 that we see at page 84?---No.

20 Do you, are you familiar with or do you know the person referred to in the letter as Lind L-I-N-D Gomez G-O-M-E-Z?---Yes. She's was a, a person that we met when we went out with friends who was looking for a position just, she was working, she was temping somewhere and we said well we're looking for, not myself but we were in a, we were in a very loud noisy place, it doesn't matter where it was, yeah, so we were all sitting down and we were all having drinks and things and it was discussed that we can, if you like, you can be a part of this company. We will pay you for doing paperwork and things like that, unrelated to the hospital this is. And, but she apparently just went to Wollongong for other personal reasons a day or so later.

30 But Ms Lazarus, do you, do you have any understanding as to whether in April, 2008 Ms Gomez was employed by Wish Consulting as a Human Resource or Recourse Manager?---That, during the discussions when she did come, four more discussions, it was discussed that would be her title. At no point whatsoever any funds were exchanged, and we didn't even get her to sign a contract because like I said, a day or so later of preparing this she basically said, oh, I've found something permanent in Wollongong and her partner moved away or something. I'm not quite sure what the detail, her personal details were. Nevertheless she went there, this was never actioned. This contract was never actioned because Jessica, she came back and told us
40 she wants to continue, take on another subject at the university. So this was just void.

And when you refer in your evidence to we, I gather you're referring to both yourself and Michelle?---That's correct.

All right. Now can I just ask whether or not you recognise on page 91 of this examination bundle, your sister Jessica's signature above the date 17 April, 2008?---Yes, that's correct.

Thank you. Now at page 92 is a letter which you appear to have signed on 12 May, 2008. Is that right?---Yes, that's correct.

And may we take it that you prepared the letter in the sense that the content of the letter is yours and you typed the letter?---Yes, it was also proofread, my work needs to be proofread and things like that and yes, but it was proofread and changed but yes, the content there is mine.

10 Proofread by whom?---By Michelle.

All right. And may we take it that the content of the letter and the preparation of that, on the letterhead of the Gynaecological Cancer Centre - - -?---Yes.

- - - was the subject of some discussion with Professor Hacker before the letter was prepared?---Professor Hacker has, Professor Hacker has seen this letter, that's correct.

20 He's saw the letter, did he?---That's correct.

At what stage in the process of its preparation did he see the letter?---He saw this letter when it was printed out on a white piece of paper and was given to him to have a look at. This was in relation to the marketing of the clinical trial in creating awareness. He, I showed him the letter and I said this is the letter, it's like a welcoming letter. He was happy with it, he didn't really care I guess at one point about this letter but he is well aware of this letter and I said, Is this letter okay in terms of information that's written there, I was more concerned about the information regarding the clinical trial. He said that's fine and it was printed.

30

So did you type this letter on the computer within the Cancer Centre?---No, oh, the first draft, yes, but then like I said, it needs to be proofread because even though this will be public knowledge, I'm slightly dyslexic. I, I can, I see words that are latter rather than forward first, that's, that's the issue in terms of speaking as well, which I'm doing a good job I think considering the pressure, I say the first, last word before I say the first word so in terms of numbers as well when I write, for that reason when I write something it needs to be looked at.

40

All right?---It needs to be corrected.

So we should understand - - -?---So it will be, there will be copies of this letter on the hard drives that the ICAC obtained from my room and my computers and things like that but that's the drafts.

Well, I just wanted to understand - - -?---Yes.

- - - and I think I have but can I just confirm it?---Sorry.

The first draft was prepared on the computer within the Cancer Centre at Randwick?---That's correct. Well, I started preparing because there was time because I, yeah.

You then took the version of the letter as prepared presumably on some form of computer stick?---That's correct.

10 So that you were able to work on it on a portable computer at home, is that right?---That's correct.

Which explains why the form of letter is on the computer that was seized by - - -?---That's correct.

- - - ICAC officers?---That's correct.

Is that right?---That's correct.

20 But ultimately after proofreading and the like, a draft you say was provided to Professor Hacker?---That's correct, 'cause I wanted to make sure that the, the information in terms of the clinical trial was to his liking.

All right?---Or approved by him.

You then say to me that you provided that draft to him for his review? ---That's correct.

30 Did you see him review it?---Yes, he read through it in front of me.

And after he read through it, what did he say to you?---He said, "That's okay."

Did he say anything else?---No. He had no issue with this letter. Like I said, I don't think he really cared at that point.

He, he was, he was content, was he- - -?---Yes.

40 - - -from what you could see and what you heard- - -?---That's correct.

- - -that a letter from the centre addressed to whom it may concern was appropriate?---Yes.

All right. And once you got his approval, you signed the letter. Is that right?---That's correct.

And may we take it that had you not got Professor Hacker's approval for this letter, you would not have printed it out on letterhead and signed it as we see it and used it?---That's correct, yes.

10 What did you do with the letter, Ms Lazarus?---It was to be part of the, like a welcoming note for anyone that wants to obtain, wants to get information in regards to the clinical trial, whether it's a funding body or patients or create sponsorship in terms of donating, donating like, like, for example, if Kleenex, if they want to, for every patient that gets screened maybe have like a, like, I'm just using Kleenex as an example 'cause there's a box here, um, be able to give them a packet of tissue. Do you know what I mean, you go to a dentist, you get, like, or an orthodontist, you get a bag and it's got gum in it and a, and a, like a disposable toothbrush.

Ms Lazarus, apart from speaking about- -?---I'm trying to explain what marketing and what the purpose of this letter is.

20 But did it actually go to anyone?---Ah, yes, it should, yes, it would have, yes.

Do you know whether it did?---Not to my best of my knowledge. That you will have to ask, I'm sure you will, ask Michelle that, in terms of marketing.

Ms Lazarus, having obtained the letter, did you in fact use it as part of any form of marketing to procure- -?---Not me personally.

- - -sponsorship funds externally at the hospital?---Not me personally.

30 All right. Do you know anyone who did?---Um, that would be the marketing ah, person, that would be Michelle.

All right. And can you tell me, please, the name of any sponsor or sponsors to whom this letter was provided as part of some marketing push to procure funding in relation to the trial?---Um, I think you've got that on a database.

40 I might have, but can you tell me, please, as your recollection best tells you, who got (not transcribable)- -?---There's 202 companies. There's over 202 companies on that database. Did you want me to start listing them, like, computer companies maybe. Um, there's um, food companies, beverage, like, you know, um, computer companies like HP maybe. Like I said, there's 220 exceeding companies on the database that you now have which was said that couldn't be found before, but apparently it is there.

So, Ms Lazarus, is your position that as you understand it, the letter of 12 May, 2008 under your hand was used and sent to potentially some 200 prospective sponsors of the clinical trial?---Might not be 200, it might be 200. I'm not, like I said, I'm not clear as to the number and the, the, and the um, the companies. Um, it was voiced in previous closed investigations that

this data base exists by me and by Michelle and the ICAC bluntly turned around and said there was no such database, but now apparently this database has come to light.

All right. Thank you?---Thank you. So - - -

If we look at pages 93 and 94 of the Examination Bundle please?---Yes.

10 And as you will see, each of these letters addressed to whom it may concern have been signed by a person identified as Ravi, R-A-V-I, Ratnam, R-A-T-N-A-M. Do you see that?---Yes, that's correct.

Now, did you prepare each of these letters?---No.

Did you have anything to do with the preparation of these letters?---Yes, I did have involvement.

20 Righto. Tell me what that involvement was?---That involvement was um, the amount that was provided for the letter um, for the um, the, the sum, and um, and the company that the letter needed to be addressed to and the clinical trial the letter needed to be addressed to. Um, this was requested by Johel Neiron um, as it was requested um, by him in previous clinical trial, both at Strathfield Private and St Vincent hospital that as letter of this nature needs to be provided to him outlining where he should put the funds in.

30 Right. So should we understand that you went to see Mr Ratnam?---That's correct, in all, in all three occasions um, even for Strathfield Private, the accounts manager for Strathfield Private was approached um, as directed by the CEO of Sydvat, Johel, that um, I need to go get a letter outlining um, where he needs to deposit the funds and um, the contact details of the accounts department and things like that. In relation to that conversation both for Strathfield and St Vincent Hospital, exactly the same thing was prepared by their accounts department and so for this as, for Royal Hospital for Women as well a similar letter was prepared, which is in front of you now.

So if we can understand as best we can the steps that were taken for these two letters to be prepared?---Ah hmm.

40 Firstly you went and saw Mr Ratnam in his office?---That's correct.

Where was his office located?---Um, very far. Um, it's, it's in between Royal Women's and Prince of Wales ah, where the accounts department is.

All right?---And up through another hallway and the last, I can tell you the layout of the office.

Well, let's not, let's not concern ourselves with that. When you saw Mr Ratnam, did you introduce yourself?---Yes, of course.

And you asked him to prepare these two letters?---That's correct.

10 And what else did you tell him as to the purpose of the letters?---Ah, for ah, a funding body needs to put through funds um, in regards to a clinical trial. Um, their request is, 'cause this is exactly what Johel had asked for last time in terms of the Sydvat CEO, Johel Neiron um, he asked that I prepare a letter with the cost centre number and the account details. So exactly the same information was relayed to him that what account details I need, I need to provide this person.

Now, you told me a moment ago that you provided the information concerning the name of the clinical trial test?---Yes, that's right. The letter says, "Re Medex Test Cervical Cancer Clinical Trial."

So that's- - -?---That's correct.

20 That's your input in each of the letters?---That's correct.

What you said it was regarding. Is that right?---Yes, yes.

You also provided- - -?---Provided to whom it may concern.

Thank you. And you also indicated that \$73,950 should be referred to in the letter as the sum- - -?---That's correct.

30 - - -required?---Yes. That sum was provided by Johel Neiron that that's the outline that I need to put through for the first payment that will go through.

And apart from those two matters, is the balance of each of the two letters Mr Ratnam's work, as best you are able to say?---That's correct.

Now, on the second letter in the last paragraph there's reference to a reference number. Do you see that, 1-5-2-1-0-7?---That's correct.

40 Can you tell me where that number came from?---Um, that number um, the accounts department person provided um, but apparently when I went back to um, the, to the centre, that's not the oncology number's cost centre.

When you say the accounts department person provided that number- - -? ---Yes.

- - -I take it you're not referring to Mr Ratnam?---No, I am referring to Mr Ravi Ratnam.

So he is the one that provided you with that number?---With that cost number, that's correct.

And when did you discover that that number was incorrect?---With the first invoice.

And what happened which led you to understand that the number was incorrect?---Um, in the requisition book that's not the cost centre number that was outlined.

10

I see. And was that because you were able to see from the requisition book the earlier cost reference numbers that had been used and it was not that number?---That's correct. And on top of the requisition book it's written in black Texta in bold.

And so once you realised that the number Mr Ratnam had identified in his letter was not the number referred to in the requisition book, you proceeded to use the number in the requisition book. Is that right?---That's correct, yes.

20

THE COMMISSIONER: Mr Alexis, is this a convenient time?

MR ALEXIS: Yes, it is, thanks.

LUNCHEON ADJOURNMENT

[12.49pm]

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