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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 WEDNESDAY 16 FEBRUARY 2011

AT 1.50PM

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

THE COMMISSIONER: Mr Alexis.

MR ALEXIS: Commissioner, before we start I understand there's an appearance for Professor Smith.

MR LONGVILLE: Yes, may it please the Commission, Longville, L-O-N-G-V-I-L-L-E. I seek leave to appear on behalf of Professor Smith.

THE COMMISSIONER: Yes, thank you.

10

MR ALEXIS: Thank you, Commissioner. I call Professor Ross Smith.

MR LONGVILLE: And whilst Professor Smith is being called there is an issue of a section 38 application, may it please.

20

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

30

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

THE COMMISSIONER: Professor Smith, do you wish to give your evidence under oath or do you wish to affirm the truth of your evidence?

40

PROFESSOR SMITH: I'm happy to give it under oath.

THE COMMISSIONER: Yes, would you swear Professor Smith.

THE COMMISSIONER: Yes, Mr Alexis.

MR ALEXIS: Thank you, Commissioner.

Sir, is your full name Ross Cyril Smith?---That's correct.

10 And are you currently employed as a Professor in Surgery, Research and Education through the Northern Clinical School of the University of Sydney at the Royal North Shore Hospital?---That's correct.

And in relation to this matter have you given ICAC investigators two statements, the first on 9 June, 2010 and the second on 16 December, 2010? ---That's correct.

20 Can I show you please copies of each of those statements. Would you just take a moment to look at each of those documents, sir, and confirm that they are the two statements to which I just referred?---That's correct.

And is the content of each of those two statements true and correct to the best of your ability?---I understand they're a copy of the statements which I have - - -

Yes, thank you?---Yes.

30 And the content is true and correct to the best of your ability?---To the best of my ability.

Thank you. I tender, Commissioner, each of those two statements.

THE COMMISSIONER: Professor Smith's statement of 9 June 2010 will be Exhibit 14 and his statement of 16 December, 2010 will be Exhibit 15.

**#EXHIBIT 14 - STATEMENT OF PROFESSOR ROSS SMITH
DATED 9 JUNE 2010**

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**#EXHIBIT 15 - STATEMENT OF PROFESSOR ROSS SMITH
DATED 16 DECEMBER 2010**

MR ALEXIS: Now, professor, should we understand that your qualifications are set out accurately in paragraph 4 of your first statement, Exhibit 14?---That's correct.

And your areas of speciality are set out in the second last sentence of that paragraph where we see reference to upper gastrointestinal and the other areas?---That's correct.

Thank you. Now, in paragraph 5 you refer to your position as Post-Graduate Coordinator with the University of Sydney, Faculty of Medicine and having held that position since 2004 and 2005?---That's correct.

10 Could you just explain to the Commissioner what that position involves in terms of you receiving students who wish to undertake PhD studies within the Faculty of Medicine?---The Post-Graduate Committee oversees all admissions to PhD. Everybody who's admitted would have a supervisor and, and as well as the Post-Graduate Coordinator depending on the, on the, whether it's in medicine or surgery or pharmacy or whatever and each, each of the applications, particularly if there's any slight difficulties would come to the Post-Graduate Coordinator to try and find out exactly the situation and to help, help the students through their PhD.

20 Now, was it that office that led you to meet with Ms Sandra Lazarus in the 2008 year?---One of the issues is because the university has strict criteria as to who will be a supervisor, they would request somebody who has experience as a supervisor for a PhD to, to carry that role. So Professor Gillett hadn't supervised PhD's before and so for that reason Sandra was directed towards me for me to assess whether she should undergo a PhD.

Thank you. Can we seek to try and tie down when that was that you first met with her? And I think attached to your first statement is a document entitled Changes to Supervisory Team Form and you'll see that the format
30 of that document has just come up on the screen?---Yeah. I actually met her on 8 August before that, but that's probably when we came to decide to proceed. So I had, I had met Sandra about ten days before that there.

All right. Nonetheless, the document assists in identifying the month of the 2008 calendar year during which you first met with Ms Lazarus and had discussions with her about what she was proposing. Is that right?---Yep, that's right.

Now, Professor, could I just understand whether or not this form is a form
40 that you signed on or around the date indicated, 18 August?---That's correct.

And is it a form that was provided to Ms Lazarus after you met with her during that month?---Normally the student would bring that form along or sometimes it's emailed to me and asked me to fill it in that way, but I can't exactly remember how, how it came to me but- - -

And after you'd signed the form and completed the details that we see written on it, did you provide the form to Ms Lazarus to take back to the university?---It would be the normal practice.

All right?---Sometimes we would fax it through but it would be normally it's taken back with the student.

10 Thank you. And is your recollection that after seeing Ms Lazarus and having signed this form that you provided the form to her for return to the university?---I, I can't exactly remember which of the ways we handled that on that day, but I would have had no reason not to give it to her.

20 Thank you. Now, you deal with the subject of meeting with and speaking with Ms Lazarus from paragraph 7 of your first statement, and could I ask you particularly to look at paragraph 8. Now, in relation to the information you set out there, namely her involvement in previous studies at Concord Hospital and Strathfield Hospital, did you ever have occasion either in August 2008 or at some other time to seek verification of whether in fact what she informed you about her experience with the Medex device had in fact occurred?---No. I, I never actually rang Professor Gillett, but shortly afterwards Sandra brought along a manuscript which looked like she had undertaken such work.

30 And if I could ask you to look at paragraph 10, you refer there to a Professor Farrell from Westmead Hospital and you then refer to a belief that Professor Farrell may have moved to another hospital et cetera and then you say, "I believe that Ms Lazarus was undertaking some type of project involving electronic recording of medical records with Professor Farrell." Do you see that?---Yes.

And again is that all based on what it was that Ms Lazarus informed you?
---At that stage it was, yeah.

Did you have occasion to subsequently seek verification of that information?---Yes, I reviewed her file at the university and there is verification that she was employed in that capacity.

40 All right. Thank you. Now, in paragraph 11 you refer to the absence of any documentary proof of her qualifications. Do you see that?---Yes.

And can I then come to the last sentence where you express the making of an assumption concerning enrolment to undertake PhD studies. Do you see that?---Yes.

Now, what should we understand by that reference, that when she came to see you, you understood or had assumed that she was enrolled as a PhD student or was she seeking to be enrolled?---She was seeking re-enrolment, having been enrolled in the past, and- - -

So when, I'm sorry?---Yeah. And, and so, but I did ask her about her previous education and she did bring me some certificates across but it wasn't something that I was very familiar with.

10 Mmm. So you understood the question at that point in time with respect to Ms Lazarus concerned her re-enrolment as a PhD student with the university?---Yes, that's right. It's not necessarily the post-graduate coordinator's job to choose to make criteria, that's, the Faculty of Medicine makes that decision, but I was just inquiring for my own knowledge.

And before she came to see you, did you have an understanding as to whether or not she, that is Ms Lazarus, had made an application to re-enrol in the PhD course?---Absolutely, yes.

And so when she saw you, that application was pending?---Was pending.

20 And was it ultimately determined?---No. She wished to be enrolled in the second semester of 2008, but to be enrolled she had to be enrolled by August and maybe the latest September and the paperwork was never completed in time for that.

So in August 2008, assuming the application for re-enrolment be successful, when was the earlier recommencement date?---It would be March 2009.

30 Thank you. Now, in paragraph 13 you set out your knowledge as to what Ms Lazarus intended to undertake with respect to the use of the device in some clinical trials. And may we take it that the information that you've set out in that paragraph and the following paragraphs, including what you've set out in paragraph 18, came from Ms Lazarus?---Ah, not, not all of it. Ms Lazarus brought, brought along some information which allowed me to judge how the Medex device worked and I was able to determine that it is a slightly abstract term, the phase angle, which, which I've outlined there, but it's, using it in different parts of the body. And I have knowledge of this because we use a similar sort of device to measure total body water in the body, and so it's the same technology but in a slightly different way and different format that the Medex device, through which the Medex device worked.

40 All right. Now in paragraph 18 you refer to a computer program that was brought along and shown to you. Was that in the form of a laptop computer that illustrated things on a screen?---That's right. It's a small computer device like a laptop computer and leads which you attach to different parts of the body.

All right. And having taken you through what was available to show you on the computer, I gather you then held some scepticism as to whether or not

the device might actually be able to detect cancer within the body?---Yeah, that's correct.

Over in paragraph 19 you tell us about an awareness you had concerning Ms Lazarus conducting a number of tests using the Medex device at Strathfield Breast Cancer Clinic at the Strathfield Private Hospital. Do you see that?---Yes.

10 Now I gather that awareness came from what Ms Lazarus informed you during your meetings with her?---Yes. Oh, she did present me with a copy of a manuscript that she had prepared from that room.

And that's what you - - -?---And she did bring some patient files with her and showed those to me.

All right. And in relation to the patient files do you recall what those files contained and how they were presented to you?---No, I can't. I can't recall that. They were like working sheets, I think.

20 And in and amongst that material that was shown to you did you see any colour graphs which were described as the resultant output from the computer following the examination of a patient using the device?---I can't remember whether each of the files had such a graph in it, but in the manuscript that she prepared there was such a colour graph.

All right. Now in paragraph 20 you tell us of an impression you gained from Ms Lazarus with respect to the Medex company as you've described it?---Ah hmm.

30 Could you tell us please what was said or what occurred which led to you forming that impression?---(not transcribable) I was interested to know whether she had interest in the company because that would (not transcribable) that the project was actually fairly close to the company rather than it being a true academic project. And sort of not necessarily good for a PhD to just be using the PhD to promote a project, a company, if you like. And so I just needed to understand that and I (not transcribable) discussing that with her.

40 And in that respect was there or do you recall there to be a discussion about funding in so far as costs might be incurred in the conduct of any trial?---Funding and costs did come up from time to time and Sandra informed me that there was some money left over at Concord Hospital which would come to help run the, the study. And she, she indicated that the company would support the work.

And we see that do we in the last sentence of paragraph 22 where you express a belief that you then held that the Medex company was putting forward funds?---Correct.

And that belief came from Ms Lazarus?---Correct.

Did you ever speak to anyone independently of Ms Lazarus concerning the subject of funding for the clinical trial at all, Mr Ross?---Not at all.

10 And before we move forward can I just go back to paragraph 21. You refer there to the files that you spoke of a moment ago on about 100 patients and may we take it that they are the patients that you've referenced in paragraph 19 from the Strathfield Breast Cancer Clinic?---Correct.

Thank you. Can I bring you forward to paragraph 26, please professor. And do you see there that you refer to a belief that before Ms Lazarus came to see you she'd been to St Vincent's Hospital, Darlinghurst and attempted to use the device to detect the presence of prostrate cancer in patients as well as the Royal Hospital for Women?---Yes.

20 Now can I just understand what you meant to convey by using the expression attempted to use? What did she say which led you to form the belief that there had been such an attempt?---She told me that she had undertaken the studies. My, my, the words attempted to use probably are my, my judgement rather than her judgement.

So should we understand that she conveyed to you that she had done tests at those hospitals?---That's what, that's what I was led to understand.

30 And might the material concerning the patient files from the Strathfield Breast Clinic, did you see or were you provided with any documents?---No, I didn't see any other - - -

Just so I can finish my question if you don't mind. Did you see any documents which corroborated or at the very least gave some support for what was referred to as prior testing of the device at either St Vincents Hospital or the Royal Hospital for Women?---I never saw such information.

40 Now, professor, can I turn some, turn attention to some, some forms and could you be shown please the examination bundle which is Exhibit 1. Could you turn to page 128 please, professor. Professor, the document before you should be a security pass application form. Do you see that? ---Correct.

And do you have any recollection of being provided with this form at any stage?---This form would, I can't actually recollect, recollect the exact form but this would be a standard process. Because I was encouraging Sandra to work within the Kolling Institute and to change her direction a little bit she would need access to the Kolling and therefore this form was, I initiated the contact with the manager to arrange for this form to get, be undertaken.

Now in some evidence that was given earlier this week, professor, in relation to the information contained on it, it was suggested that you instructed by contacting a practice manager at the Kolling building for the purpose of the employee details being completed on the form?---Yes.

Now, what, what do you say to the suggestion that the details on the form under the heading "Manager Use Only" and in particular the handwritten words "PhD student" adjacent to the words "Employee's position/title" were words that came as a result of an instruction from you?---I think that's correct. I would have said Sandra was going to start a PhD, or well my expectation was at that time in October that we'd come to an agreement that, that we would change the direction of the PhDs somewhat and that she would then get the skills to be able to do the extra part of the PhD that were necessary to be done.

Did you understand the result of the form being processed that Ms Lazarus would be issued with a photograph identification card which would describe her as a PhD student?---Well, I, I maybe didn't understand the implications of her being described as a PhD student at that stage because she wasn't at that stage but she, my expectation that she would become one and she needed that card to be able to get access into the Kolling building to do the work that we had planned.

Why was it that this form was processed in the way that you've just described and Ms Lazarus was issued with a security pass before her application for re-enrolment as a PhD student had been determined?---That, that's been pointed out to me as being, as probably being my, my over-enthusiasm to get another PhD student and, and so I, I was trying to encourage, encourage her and I realised that she only had another year to go and we'd have to get, start, she'd have to get started quickly to complete this if, if her re-enrolment was going to be in March and she had to be finished by the end of October it wouldn't leave enough time to do a PhD so I was trying to get her into the system.

But leaving aside your enthusiasm, sir, it's plain isn't it that by instructing the practice manager to facilitate the issue of a security pass that enabled her to obtain access to secure premises before her application for re-enrolment had been determined. Is that right?---I understand that.

And of course all of what I've just put to you assumed that her application for re-enrolment would be successful?---Correct.

Did you ever consider at the time that it was inappropriate to facilitate the issue of a security pass in advance of the application for re-enrolment being considered and determined favourably?---I understand that that's, that, that is not the best practice at the time.

Has anything changed since the events of August and October 2008 to ensure that security passes and like privileges are not conferred on students who are nothing more than applicant students at the time?---I spoke (not transcribable) manager spoke to me about this and she said she wouldn't allow anybody now to be, have a security pass who wasn't enrolled as a student.

10 Thank you. Can I ask you to turn to pages 130, 132 and 136 of the examination bundle please. And do you see there the copy Vendor Maintenance Forms for the various companies referred to on them?---(No Audible Reply)

Do you see those, professor?---Yes, sir.

Thank you. And in October 2008 did you have any idea or understanding as to what the companies described next to the vendor's name on each of those three forms concerned?---I've never seen these forms in my life before.

20 Now - - -?---And I've, I've never seen a blank Vendor Maintenance Form. I've got no idea what it means and what it's all about.

THE COMMISSIONER: Have you ever seen one that's filled in?---Never and, and I never had any authority to sign such a form.

30 MR ALEXIS: Sir, can I show you please the document that purports to be the original of the former page 132, that is to say the Wish Consulting document and can I also show you the document that appears to be an original of the document at page 136 and can I ask you whether having had the opportunity to look at either the original or at least a better copy of those two documents whether or not that's your signature below what's written as "Professor R Smith" adjacent to the "Authorised by" section of each of those forms?---In the second form I never sign by name as Prof Smith, .Smith, I never do that. The signature on, where I've signed, where it's been signed as R Smith, you know, it's very difficult to say it's absolutely not my signature but it doesn't have the same slope and character as my signature.

40 THE COMMISSIONER: Are you able to say, let me start again. I understand that answer to be given by reference only to the examination of the signature?---Yes, that's correct.

You have earlier said that you have never seen these forms before?
---Correct.

The inference I draw from putting the two answers together is that you're saying that this is not your signature?---Correct.

And that's, that's a careful and deliberate statement under oath?---To the best of my judgement. That's correct.

Is there any way in which you could have been given these, in the ordinary course of things, is there any way in which you could have been given these forms to sign?---I don't believe so.

Have you ever been given forms of this kind before? I presume from your previous answers that- -?---Never.

10 Never. Do you know what they're for?---Not really, but I wouldn't sign a form not knowing what it was about. Certainly the signature for transfer from, from me to the supervisor is clearly my signature (not transcribable)

I beg your pardon?---My signature is on the form in I think August where I accepted transfer of her to be, supervision to my care.

Yes?---And that's my signature.

Yes.

20 MR ALEXIS: Professor, in relation to the vendor maintenance form concerning the Complete Health and Medical Company, can I refer you to paragraph 56 and 57 of your first statement, in particular what you tell us at the end of paragraph 57 about you being on leave. Do you see that?---I'm sorry, I'm not, which one?

Paragraph 57?---Of?

Your first statement?---I've got the second statement. Yes.

30 Now, what should we understand as to the basis of you saying in that statement that you were on leave at that stage?---I was on leave from North Shore Hospital.

All right. And what, holiday somewhere or- -?---Ah, no. That stage I had resigned from North Shore Hospital.

40 I see. This is, well, let me ask you this question. If you look at the form which is for convenience up on the screen or otherwise at page 136 of the examination bundle, and if we scroll down to the bottom of the form you'll see the date adjacent to your signature as 22 October, 2008. Do you see that?---(NO AUDIBLE REPLY)

So when you say in paragraph 57, "At this stage", is that in reference to the date adjacent to your signature?---Exactly. I, I, I was not employed by North Shore Hospital at that stage, I was employed by the university and I had no rights to ask North Shore Hospital to pay for anything.

I see.

THE COMMISSIONER: And were you still occupying premises at that stage?---I, my, I have premises both in the North Shore Private Hospital and also in the Kolling Institute.

At that time?---At that time.

At that point in time?---So the Kolling Institute is, is Institute of University of Sydney.

10

Yes, I understand.

MR ALEXIS: Now, sir, in some evidence that was given earlier this week, and I have in my mind's eye, Commissioner, particularly page 100 around line 10 through to 30, it's been suggested that each of the vendor maintenance forms were provided to you by Ms Lazarus and she asked you to sign them. And at the time the Wish Consulting vendor maintenance form was provided, you were also provided with a form of contract which was expressed to be between Wish Consulting on the one hand and a Dr
20 Neiron's company, Sydvat, on the other, which related to the provision of marketing services. Now, sir, what do you say about the suggestion that you were presented with each of these forms for signature by Ms Lazarus in company with a form of contract as I've just described and you proceeded to sign each of them in front of her?---I don't believe I did that.

Now, thank you. The form at page 130, I'll withdraw that I'm sorry. No, no, it is 130, I do apologise. The form at page 130 and the form at page 132 of the examination bundle, sir, across the top of the page appears to have a facsimile transmission imprint running across the top. Do you see that?
30 ---Yes, I do.

And in October 2008, did you run a facsimile transmission machine with the number recorded at the top of each of these two forms?---That's our office fax number. I, I, I, the fax is usually run by my secretary and she has no record of that and I don't have any record of that. It is the top of ah, of our fax I guess.

And should I understand from that evidence, sir, that both you and your secretary, whose name I think is Joy- -?---Yes.
40

- - -have looked at confirmation reports to see whether or not in fact either you or she was responsible for sending these vendor maintenance forms via that facsimile machine on 22 October, 2008?---We have looked into it and we can't find any evidence that we did or we didn't. We've tried to find the um, Telstra bill to see if it was on there but we can't find that bill.

THE COMMISSIONER: All right. So, so your evidence on this point is neutral?---It's a big neutral, yeah, but my secretary has control of that part

of the office and she feels strongly that, that, that certainly three forms were not sent from the office.

MR ALEXIS: And can you tell me whether or not Ms Lazarus would have had the opportunity to use that fax machine at any time when she was in or around your office in October, 2008?---Um, well, it's not guarded with a wolf dog but it is guarded. I, I, I, I, I mean, I can't be absolutely certain that, that my secretary wasn't out or no or that didn't happen with one form or another.

10

All right. Now, finally on the subject of vendor maintenance forms, can I show you this further document, a copy of which you've attached to your statement but is not in the examination book.

Ah hmm.

You'll see it's up on the screen before you now, if that's easier to- - -?
---No, no (not transcribable)

20

Yes. And do you see that this is a vendor maintenance form with the vendor described as the Royal Hospital for Women. Do you see that?
Yes.

And if we can just scroll down the page again do we see underneath Ms Lazarus' name and signature, a signature that purports to be yours? Do you see that?---Yes, I see that.

30

And what do you say about the signature on that document?---Well, I mean, it ah, yeah, it doesn't look exactly like my signature but you don't know, on a funny day you might sign differently.

Yeah?---It doesn't look like my signature.

Can you think of any reason why in October, 2008, assuming such a form was put before you for signature, you would sign a form with a vendor described as another hospital?---No, not at all.

40

Commissioner, a copy of that document is part of Professor Smith's statement so it doesn't need to be separately tendered.

THE COMMISSIONER: Yes, thank you.

MR ALEXIS: And that might be returned. Can I move now to - - -

THE COMMISSIONER: Sorry, Mr Alexis, Professor Smith, have you ever heard of these two companies, Wish Consulting and Medical and Clinical Informatics, et cetera?---Not at all. Not at all.

Is it possible that Ms Lazarus explained to you what these companies were and her involvement in them and that you've forgotten that?---Not at all. I actually spent some time discussing financial arrangements between Ms Lazarus and this equipment. And it was always, she was always adamant that she, there was absolutely no association between her and the companies.

10 The contract, the contract that you alleged to have examined, it was a contract for the provision of marketing services?---I would regard that as completely inappropriate for an academic exercise.

And apparently the vendor maintenance forms have some connection with that contract?---Well, I reiterate I regard it all inappropriate for what I thought was an academic exercise for a PhD.

I take it from that answer that you're saying that that, an additional factor tending against you having signed the forms?---Yes. Yes. I, I have never engaged in a commercial company's research programme to promote - - -

20 Or, or approved it (not transcribable)?---Or, or approved it.

You have not approved it?---No, never approved one such, I mean all the research I've been involved in has been truly academic associated. Yeah, so obviously companies provide medicines, but I've never actually worked for a company to provide research.

30 And the provision of marketing services, is that, is that something in which your institution would be interested in?---Not at all. Well not the, the institution as a whole I can't talk for, but, but certainly myself I've, I'm not interested in, in that sort of - - -

Yes, thank you.

MR ALEXIS: Thank you, Commissioner. Professor, could we turn to page 138 of the examination bundle Exhibit 1 where you'll see a copy of an application for access to the computer network services of the hospital. Do you see that?---Yes.

40 And if you could just take a moment to familiarise yourself with the content of page 139 of the bundle on which you'll see various boxes in which various crosses have been placed to indicate the access requirements of the applicant. Do you see that?---Yes.

And just coming back to the first page on 138 of the bundle, do you see the signature beneath your name next to the description of Department Head or Controller Name?---Yes.

And could I show you the original of that application so that you can look at the signature on that document and are you able to indicate whether or not that is your signature on that document or not?---I think this could well be my signature on this document.

10 Now in some evidence given earlier this week with respect to the description on the document of the applicant namely, medical researcher (PhD student). It was suggested that that description was placed on the document as a result of an instruction from you. What would you say about that?---Well medical researcher is, is not inappropriate. We've got a lot of people who do medical research and are not PhD students. She certainly wasn't a PhD student at the time, but it was, she was, it was propositioned that she would become one at that point.

20 I don't want to step through what we've already been through in relation to the security access card, but are we in the same position there - - -?---We're in the same position. For her to undertake the PhD that I had envisaged to, to (not transcribable) to have the information about patients to correlate it all together, she needed access to the health care system to do that.

THE COMMISSIONER: Professor Smith, the date on, above your signature is 22 October?---Yes.

That's the same date was the date on which the form on 132 was signed and the form on 136?---Yes.

Is that the date, at that date I assume, I mean as I understand your evidence at that date you had no connection with, with the hospital?---That's correct.

30 But you, would that have any affect on, on your authority to sign this application for access to (not transcribable) Services or not?---I think it's a good point. I still had an appointment as a, as a professor in the Kolling Institute with the aim to doing translational research and (not transcribable) to do that. I guess I won't, I don't presume that I do have authority to, for her, to sign that for her.

40 I'm asking the question to try and find out what the probabilities you are, what the probabilities are on you signing the document at page 138?---I think it's likely that I did sign that.

Yes, very well.

MR ALEXIS: Now could you look at the document at page 142 and then I want to come back to 139. If you could perhaps hold that open. But at 142 do you see a document relating email and internet registration? And could I provide you with the original of that document to assist you with respect to the signature. And what do you say, sir, about the signature beneath your handwritten name adjacent to the words name of supervisor on that form?

---I understand the difficulty here. I think, it seems to me to be more a vertical signature to the one I used to produce. I guess, it's hard to say it's absolutely not mine, but it doesn't really look like mine.

The department which is identified about half way down that page which the form at least appears to authorise is described as the Kolling Institute. Do you see that?---Yes.

10 And so in October, 2008 would you have had any difficulty in authorising email and internet registration within the Kolling Institute for a prospective PhD student?---No. That'd be completely appropriate.

Sorry, inappropriate?---Appropriate.

Appropriate. Thank you. Just coming back to page 139 which relates to your general computer access to the network. Clearly enough the extent of access is far wider than what the earlier form (not transcribable) the Kolling Institute seems to relate to. Do you see that?---Yeah.

20 And so in October 2008 would you have had any authority or did you regard yourself as having any authority to authorise computer network access in relation to each of the areas described on page 139 and particularly may I draw your attention to the Oracle financial system?---I have, I have never had any, any authority to provide access to that.

30 So in relation to your evidence concerning what purports to be your signature on page 138 what does the fact of the extensive computer access referred to in this form tell you about whether or not you signed that document on or about the date it bears?---I would never have had knowledge of what the second page of this implied and I wouldn't have thought the hospital would ever have taken, taken me seriously to sign for Oracle financial access so I'd never, never been involved in that system.

But if you were presented with a form that had all of the boxes crossed in the way shown on page 139 is it a form that you would have normally signed or you would have questioned?---I would have questioned it. I think, yeah, I can't remember signing this form at all and I, and I, I would have, I would have been very hesitant to sign a form which gave that access.

40 THE COMMISSIONER: Is it possible that you simply signed the first page and didn't read the rest or just glanced at it in a very cursory fashion and didn't appreciate what was there?---I guess that's possible but I wouldn't normally want to do that or wouldn't normally do that.

MR ALEXIS: Now, professor, the suggestion has been made that the Vendor Maintenance Forms to which I've taken to, the Application for Access to the Computer Network and the email Internet Registration Form were all presented to you for signature by Ms Lazarus, you were observed to

look at each of those forms and then sign them in her presence. What do you say about that?---I, I, I never appreciated, if, if, if that's what she claims I never appreciated what I was signing. I, I don't believe I signed those vendor access forms at all. I, I had no, no knowledge of that and I would have never signed those at all.

Commissioner, can I tender the original Computer Access Network Form and could I separately tender the Email and Internet Registration Form, each being copied at 138 and 142 respectively in the bundle.

10

THE COMMISSIONER: These are the original documents?

MR ALEXIS: They are.

THE COMMISSIONER: Yes, the original Application for Access to Network Services is Exhibit 16 and the email of, and the email with Professor Smith's signature dated 22 October, 2008 relating to Internet Registration is Exhibit 16 and that is the original of that document, 17, I beg your pardon, the previous one was 16.

20

#EXHIBIT 16 - ORIGINAL FM IM APPLICATION FOR ACCESS TO NETWORK SERVICES SIGNED BY PROFESSOR ROSS SMITH

#EXHIBIT 17 - ORIGINAL NORTHERN CLINICAL SCHOOL EMAIL/INTERNET REGISTRATION

30 MR ALEXIS: And to complete the tender of the originals could I also tender the original Vendor Maintenance Forms for Wish Consulting and Complete Health and Medicine Pty Limited.

THE COMMISSIONER: Exhibit 18 is the original Vendor Maintenance Form for Wish Consulting and Exhibit 19 is the original Vendor Maintenance Form for Complete Health and Medicine Pty Limited.

40 **#EXHIBIT 18 - ORIGINAL VENDOR MAINTENANCE FORM FOR WISH CONSULTING PTY LTD**

#EXHIBIT 19 - ORIGINAL VENDOR MAINTENANCE FORM FOR COMPLETE HEALTH & MEDICINE PTY LTD

MR ALEXIS: Professor, a few further short topics if I may. In your dealings with Ms Lazarus did you ever see a Application for Ethical

Approval in relation to any clinical trial concerning the Medex device?---I, Ms Lazarus had prepared a document which she showed to me but it wasn't, it wasn't complete and it needed to be completed before it was submitted so it hadn't been thoroughly prepared at that stage.

Could you turn to page 151 of the examination bundle Exhibit 1 and there you'll see a document which is addressed to the Royal North Shore Hospital Ethics Committee with provision for various signatures including one for yourself. Do you see that?---Yes.

10

Do you recall ever seeing that document at all?---No.

Do you recall ever being provided with that document by Ms Lazarus?
---No.

And if you could just turn over a couple of pages, at 153 you'll see the first page of the National Ethics Application Form which goes for some pages and then towards the back of it commencing at page 913 you'll see the Site Assessment Form and the document in whole goes through to page 204.

20

Please take your time to look at the document. I wish to ask you whether or not you had ever been provided with that document or anything like that document by Ms Lazarus?---No, I've never been provided with this document but there was another document which she was preparing and, and this, this is quite an extensive online application form and I, my recollection was that there was a, like another form in preparing to make this application.

30

All right. I'll ask for Exhibit 4 to be obtained and shown to you and while that's being done can I ask you whether at any time you were asked to look at the document at page 151 or either of the two Ethics Applications from page 153 and asked to provide Ms Lazarus with your feedback on those documents?---When I was given the document that she was preparing it wasn't, it wasn't fully prepared at that stage. I maybe didn't give her a lot of feedback but I indicated to her that there was a lot more work that needed to be done and without going through every word I, I think I had difficulty saying exactly what happened at that stage but we, we never sat down with the document and went through it together which is what would have to happen to, to get it to a satisfactory standard.

40

And after considering the document which you're referring to and having made the suggestions that you did to her, did you ever hear back or obtain a response- -?---No.

- - -with a further document that had been worked up in accordance with your suggestions?---No, not at all.

All right. Now, Exhibit 4, which is the separate document you've just been shown, contains on the second page or from the second page something called a clinical study protocol. Do you see that?---Yes.

Now, I need to make plain to you that this relates to something completely independent of the Royal North Shore Hospital or the Kolling Institute, but insofar as the document that you were provided with, was it something in the nature of a clinical study protocol presented in the way in which Exhibit 4 or the attachment in Exhibit 4 was presented?---Ah, it could well be, yes.

10

All right. Thank you. Exhibit 4 can be returned. Thank you. Now, Professor, is it the case that you had a laboratory within the Kolling Institute of Medical Research?---That's correct.

And is that on level 8 of that- -?---That's correct?

- - -building?---Yes.

20

Is that a secured area in the sense that one needs an access pass to get into it?---That's correct.

Now, in paragraph 34 of your first statement you tell us of some detail concerning the proposal that you made to Ms Lazarus to conduct certain research that would involve the collection of blood samples as part of her ongoing PhD studies. Do you see that?---(NO AUDIBLE REPLY)

30

Now, in paragraph 35 you express there your understanding that she spent only one day at the Kolling Institute where she sat down and had a look at a few patient cards and then you made comment about her then not being enrolled at the university. Can you tell us what the basis of that understanding is, please?---Ah, she, she, she did visit the Level 8 of the Kolling on more than one occasion, but on, as we were trying to develop a protocol so that she could make a full ethics application, I needed to introduce her to the system that's developed for collecting information and collecting blood samples, which is really very involved, it requires a patient history and clinical information, it requires a secure area of the blood samples we get and the patients' documented information is kept in a secure area where, where they're de-identified. So it's really a very complex process of collecting blood samples. And, and, and I was, I was really very enthusiastic about collecting such samples from people who have early cancer because you might find important changes in their blood which might be diagnostically important.

40

Mmm?---So, so I was introducing her to the people. She only spent one day down at the tumour bank, she was given some cards by the tumour bank officer who managed that and, and then she didn't say very long and she said she had to go to university or somewhere else and so she left.

Mmm. So was that the extent of what you observed her doing at the Kolling Institute as to- -?---Ah, she did, on a few occasions she visited ah, she attended a meeting which we have on Monday morning where she sat at the back of the room to hear about research which was being discussed, and I introduced her to my research scientific officer who was at that stage doing her own PhD and who would have worked beside her to analyse the blood samples.

10 Mmm?---So I, so she did spend a few days up on level 8, the tumour bank's on level 1, so it's a slightly different area, and but she didn't spend a lot of time there.

And none of that had anything to do with the use of the Medex device on patients?---Not at all. It was more to do with (not transcribable) There would have been a nice comparison between the two.

20 Mmm. Now, in paragraph 46 you tell us about some observations of Ms Lazarus attending the Royal North Shore Hospital and your encouragement of her to attend regular meetings back at the Kolling Institute. Can you tell us where it was that you observed her attending Royal North Shore Hospital, appreciating of course it's a big place?---Well, well, the, the meeting room where the Kolling meetings are, are on level 8. There's a, there's a Nelson Room and it ah, and when you walk into the lab you walk past that room and you can see people sitting there. So I've observed her sitting there on a few occasions listening to the meeting, which was a Monday morning 9.00 to 8.00, 9.00 to 10.00 meeting.

30 Ah hmm. Did you ever observe her using the Medex device or seeing any patients in relation to the Medex device anywhere at Royal North Shore Hospital?---Not at all. She, she did demonstrate it to me in my office.

And apart from that demonstration in your office, was that the only time you saw it?---That's the only time I saw it.

40 Now, in paragraph 50 you tell us of a meeting that you had with Ms Lazarus in about early January 2009 where you apparently discussed her involvement with the Medex company. Now, can I understand in short compass what led to the meeting that you refer to in paragraph 50?---Ah, in ah, on 20 November in '08, somebody from St Vincent's Hospital let University of Sydney know that they felt that Ms Lazarus had been behaving unethically and that was passed to me and I sent a month of so trying to chase it up to find out the details of that. I, I spoke, there were a lot of phone calls waiting for replies and that and it wasn't until the beginning of January that I had some information about that and, and it seemed to me important to decide whether or not she was behaving unethically and I tried my best to do that and I thought I should discuss issues with her.

So the point of the discussion in paragraph 50 was to determine whether or not Ms Lazarus had any relevant connection or association of relationship with the Medex company?---Implication from St Vincent's was that she had an association, that she was shareholder or she was, or her family was, were involved with the Medex company and, and that Medex company's Website indicated that she had ethics approval to do research at St Vincent's Hospital and they felt that that was wrong because she didn't have ethics approval to do that. And, and so that was the issue that was being explained and, and they were very concerned that, that she had financial involvement with the Medex company.

In paragraph 52 you tell us that you did not know nor were you aware of her involvement in the companies set out across the top of the next page of your statement, page 15. May we take it that during the meeting that you had with her in early January 2009 those companies and her relationship with those companies was never disclosed or discussed with you?---Never discussed.

And, now, when was the last time you spoke with Ms Lazarus?---I can't recall exactly, but it would have been February 2009 or something like that.

And up to that point in time, had you any, had you ever seen any results from any testing of any patients at the Royal North Shore Hospital, leave aside the area of specialty, but any patient from North Shore Hospital using the Medex device by Ms Lazarus?---No, not at all. And given that I was supposedly her supervisor I would have expected to see them.

Yes. And had you been provided with any data from any such examinations of patients using the Medex device for consideration?---Not at North Shore Hospital. I did at, at, at Strathfield Private, as I said.

Apart from the material that I think we've been through from Strathfield that she provided to you- - -?---I haven't got- - -

- - -you saw no other data?---No.

No reports or other publications concerning the performance of any tests at Royal North Shore?---Not at all.

Do you recall ever meeting with or communicating at all with Ms Lazarus' younger sister, Michelle?---No, I never met her younger sister.

Are you familiar with the following medical practitioners, Professor Burton, Dr Valdermere, a Dr Sywak, S-Y-W-A-K, a Dr Hugh, a Dr Back and a Dr Pavalakis?---Yes, that's correct.

Have you at any time provided them with any instruction or direction or indeed have you communicated with any of those doctors at all in relation to

the performance of any clinical tests using the Medex device by Ms Lazarus?---I have not.

Have you had any communication with any of those medical practitioners concerning the authorisation of the payment of invoices using the appropriate forms?---Dr Hugh spoke to me about it after the event to some extent and, and he didn't understand, he didn't, if he had signed it he didn't know the reason for doing so.

10 And finally in your second statement at paragraph 22 on page 6 you say there to the best of your knowledge and belief no actual clinical trials had ever occurred at the hospital or the Kolling Institute of Medical Research. Do you see that?---I think the statement is (not transcribable). You have to understand these doctors all work away from where my offices are and I wouldn't necessarily be in a position to observe any such undertakings.

Well that's why I'm asking you about what might at first value appear to be a rather broad statement. In so far as your evidence is concerned with the conduct of actual clinical trials how should we understand what you've said
20 in paragraph 22 to be understood?---Well, I have knowledge of any, put it that way.

THE COMMISSIONER: But you can't, you're not in a position to say that it might not have occurred - - -?---I'm not in a position - - -

- - - outside your area outside your knowledge?---Yes. But I have no knowledge that it did.

30 MR ALEXIS: And I gather as the primary supervisor of a PhD student undertaking the clinical trials as part of her studies is it, something that you would have expected to know something about?---Yes. To some extent for the project to have been really successful, Sandra had to make contact with all those doctors to make relationships. But there's no way that she should have undertaken that until she had ethics approval through.

But you had no communication with any of those doctors - - -?---No.
- - - to understand anything about the conduct of any clinical trials. Is that the position?---That's the position.

40 Yes, thank you, professor. That's all I have Commissioner.

THE COMMISSIONER: Thank you. Your reference to ethics approval, I mean am I, do I understand correctly that what you mean is that without the Ethics Committee approval none of those doctors is likely to have participated with her in the trials or assisted her in doing it?---Yes. None of those doctors are clinical doctors and don't understand research and research process. But really to collect patient information, the details about their, their disease and document it, you need to have ethics approval. It's

absolutely correct. And, and so (not transcribable) to take those trials unless you have ethics approval.

Yes, thank you. Ms Soars?

MS SOARS: Commissioner, pursuant to an agreement I had with my learned friend, I haven't been able to discuss Professor Ross Smith's statement with my client and nor some of the additional matters that have just come up.

10

THE COMMISSIONER: When did you get the statement?

MS SOARS: I received it last night, but I wasn't able to discuss it until he'd finished the evidence on Royal North Shore, which I think (not transcribable)

THE COMMISSIONER: How long do you need?

MS SOARS: Just ten minutes.

20

THE COMMISSIONER: Yes.

MS SOARS: And could I have access to the original documents (not transcribable) Professor Smith?

THE COMMISSIONER: Yes. We'll adjourn for ten minutes.

SHORT ADJOURNMENT

[3.05pm]

30

THE COMMISSIONER: Ms Soars.

MS SOARS: Professor Smith, I take it can I that the two statements that you've made are as at today's date true and correct to the best of your knowledge and belief?---They are true and correct and there, there may be other information which I've subsequently found.

Yes?---But they are correct as far as I know.

40

And there was nothing that you wished to change in relation to your statements before you gave evidence today?---No, there's nothing or there, I've mentioned the date of 20 November which doesn't appear in these statements and that would appear to me to be an important date but I've told you about that today.

Yes. And Professor Smith, you have according to your statement at paragraph 4 and the evidence you've given many roles that you were fulfilling in 2008, is that correct?---Yes.

And you were I take it a very busy man, is that correct?---I try to be busy.

And, I mean for example - - -

10 THE COMMISSIONER: I've never met anyone who would answer that question no.

MS SOARS: Thank you, Commissioner.

And in your role as graduate coordinator, I mean, one of your roles was to encourage students, you agree with that?---Absolutely.

And that was something you undertook to do?---Absolutely.

20 And you sent a letter which you refer to in your statement which is dated 31 October, 2008 to David Baxter, do you recall that?---Yes.

I just, I apologise, Commissioner, I don't have the bundle reference to that, I'm told it's page 150, Commissioner. Do you have the evidentiary bundle in front of you, Professor Smith?---I have no - - -

THE COMMISSIONER: No, it's this white bundle?---Yes.

At 150?---Thank you.

30 MS SOARS: Could I just ask you to read that letter, Professor Smith.

THE COMMISSIONER: To yourself.

MS SOARS: To yourself, thank you?---Thank you. Fine.

And it was your belief, wasn't it, at the time you wrote that letter that Sandra Lazarus was a committed student with a desire to complete a PhD? ---Yes.

40 And obviously that was your belief as at 31 October, the date you wrote the letter?---Yes.

And I think you've given evidence haven't you that you were quite pleased at the prospect of having her as a PhD student to assist you?---Absolutely, yes.

And as at 31 October, 2008 and based on your own experience with Sandra you had no complaints with her, is that correct?---At that stage, no.

And based on your dealings with her up until that date you had, you had no reason to think she hadn't acted entirely legitimately or appropriately?---No.

Is that correct?---That's correct, yes. A slight issue was that sometimes she wouldn't come to appointments and come at other odd times which was slightly annoying but apart from that - - -

10 And you're saying this occurred prior to 31 October, 2008?---(No Audible Reply)

Yes. But that was the only issue, perhaps a bit of tardiness or a lack of respect for punctuality, that sort of thing?---Yes.

That's correct?---That's correct.

20 And you've given evidence today that you were prepared to sign various forms to allow Sandra Lazarus to be given a security pass in anticipation of her enrolment as a PhD student and you were happy that she could use that pass in the work she was, was doing?---Ah - - -

At that stage, notwithstanding she hadn't in fact completed re-enrolment? ---Yes, the pass was to give her access to, to a desk in Kolling where she could have a focus and where she could develop the protocol for Application for Ethics.

30 Can I show you the document which is Exhibit 16, the FMIM application for access to network services. For everyone else there's a copy at page 138 of the bundle. Professor Smith, is that your signature on that document?---I think we've been talking about this before.

We have. And I'd like to have an answer, please, again?---Again, I, I can't be a hundred per cent sure but it could well be my signature.

40 Thank you. And I'll show you a document which is Exhibit 17, the original. And again my learned friend may help me with the number in the bundle. It's at page 142 of the evidentiary bundle. And although you may have been asked this a few times today, just in order to be perfectly clear, could you tell me, is that your signature on that form, the Northern Clinical School Email Internet Registration document at page 142?---I can't say that it isn't but it doesn't look exactly like my signature.

But it's true, isn't it, you can't on your oath deny that that is your signature?---I can't say absolutely it's not.

I know. So you agree with me you can't on oath deny that that is your signature?---(not transcribable)

Yes, thank you.

THE COMMISSIONER: I can't agree that it is yours either, you know. I don't know where we get with that, but anyway.

MS SOARS: Well, could you have a look at that document which is at page 142 of the evidentiary bundle.

10 THE COMMISSIONER: The fact is that you're uncertain about the signature?---Yes.

It could be and it might not be.

MS SOARS: And, but there was no reason for you not to sign that sort of form for Sandra Lazarus at the time, given your belief as to her willingness to undertake PhD studies, is there?---No. I would want her to have email access.

20 Correct?---Absolutely. But I'm not sure that I would want her to have access to, to other things which she had access to.

But it's entirely possible that you signed that form quickly without perhaps paying it too much attention. Is that correct?---The front of the form doesn't say anything about anything else. Um, ah, and I could have signed out without knowing that there are implications which I didn't understand.

And I'd like - - ?---Those, those implications ought to be checked by somebody else.

30 THE COMMISSIONER: I'm not sure, were you referring to the document at page 142 or 146, Professor Smith?---(NO AUDIBLE REPLY)

MS SOARS: I was referring to page 142 in that- - -

THE COMMISSIONER: Yes, I know, but I'm not sure whether Professor Smith realised what that document was.

MS SOARS: I see?---Yeah. O.K. No, I was thinking about page 147.

40 I see, so there's been confusion.

THE COMMISSIONER: I think that Professor Smith's evidence is, then you would agree that there would be no reason for you not to sign this in the light of your attitude generally at the time to Ms Lazarus?---Absolutely.

Can we move on from there? The document, and the document in which Professor Smith had reservations is the one at 146.

MS SOARS: Yes, I'm moving to that, Commissioner. I was just laying some groundwork. Thank you. Can I show you the documents, well, I'll show you them one at a time I think, to avoid confusion. There's a document which is Exhibit 18, the vendor maintenance form for Wish Consulting. And again I'll, my learned friend can perhaps assist me with the bundle reference. 132. And I'm putting to you, Professor Smith, that as at 22 October, 2008, in light of the things you've agreed that you, you had no concerns about Sandra Lazarus and you had accepted her as an enthusiastic possibly enrolling in a PhD course, but you had no reason if that form was put in front of you not to sign that form and that you in fact did sign it?---I, I would never sign a vendor maintenance form.

And, Professor Smith, I put it to you that that is in fact your signature and there's no real discernible difference between- -?---I never sign myself as Prof R Smith.

Well, can I show, can we look at the form next to which you signed Prof R Smith. Can you see that?---Mmm.

20 You see on- - -

THE COMMISSIONER: That's on page 132, is it?

MS SOARS: It's on page 132 at the point, sorry, Commissioner, the authorised by, it, it has, it requires a name and title to be completed. So it's correct your title's Professor. Is that, is that correct?---That's correct.

And obviously we know your name. So it's entirely possible when signing that form that the expectation is someone would write not only their name but their position?---Well, in that light of what you're saying, the name and title is your name and title, not your signature and (not transcribable) is, is printed, so- - -

THE COMMISSIONER: There's a curious thing, there's a curious thing about this form, it's got name/title and then in handwriting in script there's Professor R Smith, then underneath that is signature and there's Professor Ross Smith printed. And one interpretation of this is that the person who wrote Professor R Smith and Professor Ross Smith transposed or didn't realise, didn't put the signature in the right place and didn't put the name/title in the right place because if you look at the, if you look at the other forms and other, there's another example at, where was it, at, yes, thank you, 136. You look at that, you get name/title, Professor R Smith, and then signature is in handwriting. Do you (not transcribable)

So there's a curiosity about this?---Yes, yes.

And I think any understanding of what happened her has to understand the curiosity as well.

MS SOARS: So I'm just putting to you there's a possibility given that someone has signed next to the name and title spot that in doing so you would write Professor R Smith, and I'm putting to you that there's a possibility that you in fact did that, Professor Smith?---Ah, I don't believe I did it, certainly now knowing that it was a vendor maintenance form, which I would never sign.

10 Okay. But you accept, don't you, that there's a possibility that you may have signed the form without precisely knowing what it was for?---You mean I was tricked into it?

I'm just putting to you there's a possibility?---(not transcribable)

I'm, I'm, I'm suggesting that perhaps you signed it without reading it properly?---I wouldn't have done that.

Given your belief?---No.

20 Can I show you the document which is Exhibit 19, a copy of which is at page 136 of the evidentiary bundle.

THE COMMISSIONER: 136 did you say?

MS SOARS: Yes, Commissioner.

30 Again I'm putting to you Professor Smith that as at 22 October, 2008 if that document was put before you there'd be no reason, given your belief of Sandra Lazarus that you, you wouldn't sign that document. Is that correct? ---I would not sign this document if I knew what this document was. And I don't believe that's my signature.

But do you accept that there's a possibility that you may have signed that document not fully understanding what that document was for?---I don't believe so.

40 There's just one further matter, which I need to get instructions, Commissioner. Professor Smith, you gave some evidence about reviewing some files that Sandra Lazarus took to you. Is that correct?---That's correct.

And am I correct in saying that you thought you reviewed quite a number of files?---She brought, that was in, in September.

2008?---2008. She brought along a Medex device and a number of files which she'd collected at Strathfield Private.

And by files I mean patient files containing - - -?---Well I can't remember the exact nature of them, but there were a number of documents.

And how are you, are you clear that they were files in relation to trials carried out at Strathfield Hospital?---Yes.

And what's the basis of that?---Because she, she came along with a summary of the data and she put it together and I think, I believed it was, there was no, I can't remember seeing Strathfield Private letterhead or anything like that. But then you don't always collect data on letterhead of the hospital where the data comes from.

10 Is it possible that Sandra Lazarus showed you files relating to clinical tests having been carried out on prostrate patients at Royal North Shore Hospital?---Well she hadn't started to do that study at that stage. This is September, 2008.

And is it your evidence that at no later time she came to you and showed you the results of any clinical trials on prostrate patients?---No.

That's correct. That's all, Commissioner.

20 THE COMMISSIONER: Yes, thank you. Mr Hogan.

MR HOGAN: Thank you, sir. Good afternoon, professor, my name is Hogan and I represent Michelle Lazarus and I wanted to ask you some questions on two topics. You gave some evidence that you spoke to Dr Thomas Hugh about whether he had signed certain documents but it might have been after the fact you had the conversation with him. And I think you said that he said that he'd signed the documents he wouldn't know the reason for doing so. Did he tell you that some of those documents were indeed requisition type forms which related to marketing services?---No, he
30 wasn't, he wasn't explicit about what it was for. But it was related to the Medex device. So marketing services or for utilisation of it.

In relation to marketing type services, assuming that this Medex diagnostic tool, this Medex test unit, that there was an ethics approval in place and assuming that it was something which allowed the device to radically assist the medical environment in early detection of cancer, so all of those (not transcribable). Wouldn't a hospital which was involved in the clinical tests for such a programme, wouldn't the hospital derive some benefits by being the hospital that was involved in the trials and then the evolution of this
40 ground breaking product (not transcribable)?---Yep.

So wouldn't there be benefits (not transcribable) by the hospital which could be promoted by market services?---Possible as intellectual property and as a business (not transcribable). And sometimes they get involved with some newer discovery (not transcribable) hospital. But marketing is not really, the hospital doesn't have funds to (not transcribable) patients let alone market. It's not something - - -

But certainly a hospital being involved - - -

MR ALEXIS: Commissioner, I hate to interrupt but I wonder if Professor Smith could move forward towards the microphone, I'm having trouble hearing him and I'm sure there are others as well?---Sorry about that.

MR HOGAN: Obviously a hospital like Royal North Shore Hospital would support a prospect for researching in early disease detections and like that. Yes?---Yes. The hospital is, has a desire to help develop research.

10

And also that there are a number of clinical trials being conducted and hopefully will result in innovative diagnostic tools being developed?
---Exactly.

20

And assuming that, that in this matter you were told by Ms Sandra Lazarus that the, the company associated with Medex was providing the funds to, for the clinical trials that were proposed and your evidence is that it's, that's common for pharmaceutical companies, medical companies to provide the funds the whole of the trial. Could there be a situation where funds are paid into a hospital trust account fund where the monies go out of that fund to pay for the trial?---To pay for the trial?

30

To pay for researchers doing the trial?---It could go in a trust account to pay for the research staff undertaking the study. And that could be, I mean sometimes a study requires a large number of people to measure information which is extra to the patients care. And it would be important to, I mean the hospital wouldn't have funds for that so if a company wanted to develop a project and they would, they would provide funds for salaries involved. And that would often work through a trust fund.

40

And obviously to your knowledge the pharmaceutical company or the medical company, they're very interested in marketing?---Yeah.

Yes. And is it the case that if there was marketing, and I'm talking about proposals being put out to the community for private (not transcribable) sponsorship for a lot of money to go to the, go to the funding of this hypothetical clinical trial, that's something the hospital would be interested in, where's the funding coming from, is there going to be more private ownership?

THE COMMISSIONER: What is the question?

MR HOGAN: The question is that, that the hospital would it not, would be interested in that there is funding available?---I think my previous statement is correct. No, the hospital doesn't have money to engage in such activities. There's just not enough money to go around to manage the patients anyway and they, they don't have the funds for, for promotion of, of this sort of thing. If, if for instance they discovered some wonderful new treatment

then it would go to the intellectual property department who would then set up a business relationship with the company. And then they would manage that external to the hospital itself and provide some sort of royalties back to the hospital maybe. But that's how it would work. You know, it wouldn't be a casual relationship.

10 All right. If the trust fund was set up and funds were put into it from the parent company, the pharmaceutical company or medical company, then would the hospital really be concerned about how funds are paid out of the trust account fund for various matters?---Absolutely. The hospital is involved in, in everything with the trust fund person. I have a trust fund there and I have to manage that with the department of surgery business officer. And, and, and even though I put the money in there I have to beg to get it out sometimes.

20 And finally - - -?---I can just tell you I have a, a PhD post-op person whose been paid under a lower rate than she should be and it's taken months and we still haven't got her pay increased, even though we've got the money, put our money in. So it's a very tight system. It's not loose.

MR HOGAN: Dr Gil Burton, have you had any conversations with him in relation to whether he had contact with Michelle Lazarus?---I, I have no idea.

What about Dr Kenneth Vaux?---I, I do not know whether he's had any relationship with her.

Yes, thank you, sir.

30 THE COMMISSIONER: Mr Lynch?

MR LYNCH: I have no questions, Commissioner.

THE COMMISSIONER: Yes, thank you. Mr Alexis?

MR ALEXIS: Your Honour, Commissioner, I understand that my learned friend wants to raise a further topic with this witness.

40 MS SOARS: With leave just to clarify the end point in his paragraph of the second statement, of Exhibit 15, its paragraph 8, Professor Smith. Do you have that?---I think so.

When did you make those inquiries?---We made those inquiries knowing that the ICAC inquiry was, that the ICAC investigation was undertaken, being undertaken.

I see. And, and can you give us an approximate date as to what you're talking about?---Oh, January of this year.

January 2011?---2011, mmm.

And that was how many years after Sandra says that she was in the Kollings Institute?---She was there in, in January/February 2009.

So - - -?---Two years.

10 - - - two years after. And what were those inquiries that you made?---We, we looked at the desk where she sat and where the desk that she sat on level 9 and we looked in the drawers and in the cupboards and we couldn't find any files.

But you accept it was two years after don't you?---Absolutely.

And what, to the best of your knowledge were any searches undertaken any earlier than that?---I had no need to, no reason to, to look before that.

Thank you.

20 THE COMMISSIONER: Finished?

MS SOARS: Yes.

THE COMMISSIONER: Mr Alexis?

30 MR ALEXIS: Just arising out of, out of that, professor. If I could ask you to assume that in the area that was just referred to there were files or other materials from a PhD student conducting research at Kolling if in circumstances like we have here the student doesn't return to the institute for whatever reason for some period of time is there any particular practice with respect to the storage or disposal of the sort of materials that I've just described?---No, not really. Outside my office there are a line of desks, at least four or five and one of those was allocated to Sandra and while other people have used those desks they've not thrown anyway to my knowledge.

And you told me I think when I asked you this earlier that your last communication with Ms Lazarus was in about February 2009?---About then, yes.

40 From about that time until you were spoken to by the ICAC investigators are you aware of whether or not her desk or the area that was allocated to her had been assumed by another student or another member of staff or some other person?---Yes, yes, another student had used that desk and when we looked at it we found some of his goods but we didn't find anything related to Sandra's work.

And are you aware from that student whether or not when they commenced to use that area there was any materials left over or stored by Ms Lazarus or anyone else?---I was not made aware of that.

All right. Yes, thank you, professor. Commissioner, I have nothing further if Professor Smith could be excused from further attendance.

THE COMMISSIONER: I'm sorry, Mr Longville, I haven't asked you, I beg your pardon.

10

MR LONGVILLE: I have no questions, Commissioner.

THE COMMISSIONER: You're excused, professor. Thank you for attending?---Thank you.

MR LONGVILLE: Could I be excused as well?

THE COMMISSIONER: Certainly.

20

MR LONGVILLE: Thank you?---Can I give you back some of these things.

THE COMMISSIONER: We'll put them in a desk?---(not transcribable)

THE WITNESS EXCUSED

[3.54pm]

30

MR ALEXIS: Commissioner, as keen as I am to use every minute my application would be to continue and endeavour to complete the examination of Ms Sandra Lazarus this afternoon which I would presently estimate to be in the order of 20 minutes.

THE COMMISSIONER: Yes, very well.

MR ALEXIS: Thank you. Could I recall Ms Lazarus?

THE COMMISSIONER: You're still under your oath, Ms Lazarus.

MR ALEXIS: Ms Lazarus, before Professor Smith was called I was asking your some questions concerning the payment of moneys that you indicated to the Commission you understood had been made by Dr Neiron or companies associated with him in relation to the conduct of the clinical trials at the Royal North Shore Hospital. Do you remember that subject?
---That's correct, yes.

10

And the course of your evidence in relation to the achieving of milestones and the payment of various sums of money by Dr Neiron to make up the 600,000 that you referred to - - -?---Ah hmm.

- - - you said I think that Dr Neiron was provided with an opportunity to inspect some patient files and the test results in relation to those patients that you had examined at North Shore using the Medex device. Do you remember that?---Yes, that's correct, that's correct.

20

Now, firstly could I ask of you when was it that Dr Neiron was given the opportunity to look at the patient files and those test results?

THE COMMISSIONER: At which hospital?

MR ALEXIS: I'll come to that.

When, when are we talking about, Ms Lazarus?---Oh, whenever I reached 50 patients at, at any, at any hospital he would come and have a look.

30

All right.

THE COMMISSIONER: Every time you reached 50 patients he would come and have a look?---That's correct. He insisted upon that.

And what, you reached 50 patients about four times?---That's correct, and the pilot study when that was finished he would come and have a look.

So that means that there's at least five visits by him looking at files?
---That's correct.

40

MR ALEXIS: And although I'm reluctant to go back there, if I can go back to the Royal Hospital for Women - - -?---Yes.

- - - should we understand that in relation to the work that was conducted there on patients using the Medex device - - -?---Yes.

- - - there were opportunities provided to Dr Neiron to look at the patient files and the test results from each examination?---That's correct.

And should we understand from that that he had access to and was given the opportunity to look at the material that you had put in the plastic sleeve with respect to each patient?---That's correct.

Now, at the Royal Hospital for Women when Dr Neiron examined that material were you with him?---Yes, that's correct.

10 Were you with him throughout the examination of every file that you made available to him?---Yes.

So you, you had - - -

THE COMMISSIONER: Mr Alexis, I beg your pardon.

MR ALEXIS: I'm sorry, yes, of course.

20 THE COMMISSIONER: I just want to make sure that this is correct, when you talk about patients' files what do you mean?---Can I be shown, if it's allowed the files, the white folder?

MS SOARS: Commissioner, I think my client's referring to the Strathfield files which she's wanting to refer to by example?---Because I think there's a misunderstanding between the files that are the patient files and the files that are the actual patient files. Can I be permitted to show that if that's okay?

30 MR ALEXIS: Commissioner, I understand I think what's being referred to and if I might be permitted to deal with it but could I just ask for a short indulgence. I can deal with it now, Commissioner. Now, Ms Lazarus, you wish to refer do you to material contained in some white folders that related to work that was done by you at the Strathfield Private Hospital in relation to patients of the Strathfield Breast Clinic?---That's correct.

Okay. Now - - -?---If you have a look at the sorry - - -

Could, could I show you - - -?--- - - - the first folder, not the second folder. It's the first folder. So it's that one.

40 Now for the purpose of identification is it correct that each of the two folders - - -?---Yes.

- - - that I'm dealing with - - -?---Yes.

- - - were obtained by ICAC investigators on execution of a search warrant of your home?---That's correct, I was told to take these one's home because of the private hospital, they don't store research information. I inquired as to where I should keep them and I was told just store them at home, that's what I was instructed.

So your evidence is that the documents create as part of the work that was undertaken at the Strathfield Rest Centre which included information concerning particular patients was - - -?---That's correct.

- - -material that you were permitted to take home and retain at home. Is that right?---That's correct, yes.

10 Could I take out of the first of the two folders a plastic sleeve of documents which has a number 1 in the top right hand corner and show that to you.
---Ah hmm, yes.

And could you pull the material out of the plastic sleeve and should we understand that the documents comprised in the plastic sleeve comprise firstly a form of consent that appears to have been signed by a patient on a particular date - - -?---That's correct.

20 - - -together with your own signature there described as signature of investigator?---That's correct.

And should we also understand that there is a copy of some correspondence concerning an examination of the patient conducted by Associate Professor David Gillett.---Just, that's correct.

30 And we should also understand that in terms of the documentation retained in the sleeve there is a further document from Associate Professor Gillett relating to the question of whether or not the Medex Test Graph was either positive or negative with respect to the indication of breast cancer or breast disorder?---That's correct.

And the following document is the colour print out that was illustrate at Exhibit 9 yesterday.---Ah hmm, that's correct.

And that relates to the patient that is referred to in the consent form and in the two letters under Professor Gillett's hand.---That's correct.

Is there anything else in your sleeve?---No, that's it.

40 All right. So is that the material that we should understand comprises the patient files - - -?---Yes.

- - -to which you were referring to as material that Dr Neiron was given access to at the Royal Women's Hospital.---That's correct and the Royal North Shore - - -

THE COMMISSIONER: Who compiles these files?---I did.

So they're your files?---Yes, they're patient files for the clinical research.

Yes, I understand that but it's not, it's your patient files - - -?---Yes.

- - -not the, not the hospital's patient files.---No.

I understand.---And no, so - - -

Had you compiled, did you compile patient files for each of the patients to whom you administered the tests?---Yes, that's correct.

10

And did you keep them at home?---No, no, those ones were left at the Royal Women's Hospitals where I was telling you with the Medex devices and at the Knolling Building (not transcribable)

So when Mr, Dr Neiron came, you showed him your files relating to the patients to whom you had administered the tests?---That's correct, first - - -

I understand that. And the files contained the same material at what Mr Alexis has described in the last series of questions that he's asked you.

20

---That's correct including the data that was collected from each patient in terms of results by conventional screening.

MR ALEXIS: All right. Now in the questions that I've asked you in terms of the content of what you've described in your evidence as the patient file - - -?---Yes.

- - -is there anything you need to add to ensure that we have a full and complete description of that material?---Yes, um - - -

30 What is that?---There's also, if you go to the front - - -

All right. Well, I might just get the sleeve with number 1 on it back from you so that we don't get lost. Now where should I go now?---Um, if you go to the front there's another plastic sleeve, it contains a patients list, that one, yes.

Can I just show you that sleeve out of the folder and is it correct to describe the content of that sleeve as containing a patient list on a daily basis for - - -?---That's correct.

40

- - -Associate Professor Gillett - - -?---Yes.

- - -commencing on a date in November 2007 and ending on a date in February 2008?---Yes, that's for 100 patient for that folder. There will be another set of patients list for another set of 100 patients starting in folder number 2 but if you have a look at this one, that's the first patient, the first set, first day I started at Strathfield Private. It started on 6 November starting at 7.15 which was the first patient he saw until about noon, 12.00pm. I screened seven patients which are highlight and the results are

there. So on any given day between five hours I'd be able to screen seven patients, that's my first day. By the time I finished 200 patients I could complete ten patients in five hours that was outlined by you whether I could finish something in 20 minutes. Yes, that's correct, in 20 minutes I was able to finish each patient we accrued and finish as evidenced from that. Also, when you notice the date, it 6th of the 11th this is before any ethics approval was given. Ethics approval for this trial was given after 6th of 11th, 2007. The approval for this clinical trial was given in 2008. I had full consent from the Professor's supervising because their clinic and their office are in one. They sit in the office and clinic and they are face to face to me when I'm recruiting in the waiting room. They knew exactly was happening on 6th of 11th, 2007 because they reviewed each patient and the Medex Trial results and signed off on that. On 200 patients which they sat and looked. The same thing was carried out with Neville Hacker. If you, sorry, but there's another folder in there, I'm just explaining to you what we were looking for.

We'll keep going.---And what's missing. There's another folder in that bag like a booklet - - -

You're directing me to the other folder?---No, no, just the same like you took for the one you - - -

(not transcribable) copy back in the sleeve please.---Sorry. If this is what the patient list that I was spoken to you about that I get from the receptionist.

So is your evidence to the Commission that as is illustrated by the patient list for Dr David Gillett at Strathfield Private Hospital - - -?---Yes.

- - -a list was provided to you at the Royal Hospital for Women - - -?---And Royal North Shore but their clinic is the general list, they have all the patients coming through because they were the patients that are going for screening as well for conventional screening. So there would be patients for Royal North Shore Hospital that will have abnormal pap smears, they are, I've already stated in previous statements.

Let's just stick to one topic at a time.---I know, I'm just trying to explain.

So are you telling the Commissioner that the patient file, if I can come back to that because if what you said concerning Dr Neiron that has lead me to ask you these questions if you follow.---Yes, yes.

When you said in your evidence that you gave Dr Neiron access to the patient files - - -?---Yes.

- - -we should understand that to include the appointment list of - - -?---Yes.

- - -Professor Hacker - - -?---Yes.

- - -the appointment list of Associate Professor Marsden at the Royal Hospital for Women?---That's the general list that, general, that's the appointment list for the daily appointments, yes.

And in relation to that list should we understand that those patients that you are said to examined you highlighted?---That's correct.

10 And they were the patients that were identified by the clinical nurse specialists?---Um, they included but did not, were not limited to that, no.

All right. I'll come back to the detail of that. But just going back to Strathfield Private, you're not suggesting for a moment are you that whatever ethical approval or otherwise that occurred - - -?---No.

- - -at the hospital had anything to do with your work at - - -?---No.

20 - - -at Royal Hospital for Women or Royal North Shore are you?---No, not at all.

All right.---The reason I've suggested that is to let you know that the basis that I could continue researching with ethics approval was from day 1 because the first patient I screened was the 6th of the 11th which we didn't, hadn't received any ethics approval, 2007, and ethics approval was approved in 2008 at which point no one told me otherwise that I could not see any patients, and I – sorry, there's another folder there.

30 THE COMMISSIONER: Are you talking about Strathfield now?
---Strathfield But no, but the assumption where I can continue and even, even Neville, Neville Hacker when, and I told him that I had seen patients or potentially seen patients the Ethics Committee hadn't contacted him as far as I knew in terms of approval and if you have a look at the ethics application that the approval does come which you have, the ICAC has an original copy of, it doesn't come to me at all. I am not aware of the fact when ethics approval is given or when the submission of an ethics application is knocked back. All contact is made directly with the principal investigator which is the supervising professor. As an example the approval which you have a copy of, all letters went out, all written correspondence
40 from the Ethics Committee went out to, well, at Strathfield for example, went out to David Gillett and Hugh Carmalt in the same way when an ethics application was knocked back at Royal Women's Hospital the correspondence went directly to Neville Hacker. It wasn't cc'd to me or anything so - - -

Right?--- - - - for me, for him to even think about considering how many tests, how much research clinical trials he has conducted, he states there and say oh, I didn't know, he's going to take on face value what I said, that

ethics approval has been given is absolutely ridiculous because there's no way a person who's in research (not transcribable) to turn around and say that he's taking face value that I'm not allowed and considering his clinical nurse is telling him I'm looking at potential patients to not turn around and stop me?

All right?---Don't you think that's, sorry, I just wanted to get that off my chest.

10 Thank you?---Sorry.

Now, can I bring you back to Dr Neiron and looking at the patient files?
---Yes, sorry.

You've described I think fully and completely the content of the files that were made you say available to Dr Neiron haven't you?---Yes.

Now, can you tell me when it was at the Royal Hospital for Women that Dr Neiron attended that hospital with you to look at the patient files as
20 you've described them?---Oh, it would be mid to late 2008.

Where did you conduct the examination of those patient files with him?
---It was in the main office area, I could illustrate it by that diagram.

MS SOARS: If the witness could be shown that exhibit.

THE COMMISSIONER: I beg your pardon?

MS SOARS: Could the witness be shown Exhibit 12 to identify exactly
30 where she says it was?---The main office where the, there's a desk with the three computers on there, the main office, so right across from Helen's, the reception area basically where the receptionist sat. He read through, I went to the back, to the filing - - -

MR ALEXIS: Before going on, can you just tell me please by reference to the words "main offices" - - -?---Yes.

- - - are you speaking of a desk in the area which is below the word
40 "offices" as drawn by Nurse Barlow or the area above?---Above, the big, big U-shape.

All right. So if one was to come through the doorway as indicated on the diagram one would make a left-hand turn and occupy the desk area as illustrated by the large U-shape - - -?---That's right, there's a - - -

- - - drawn on the diagram. Is that right?---There's no, there's no, that line shouldn't exist. There's no barrier there. You just walk right in like that.

All right. So that's the area that you say that you sat down with Dr Neiron and you and he went through the patient files as you've described them?
---That's correct.

All right. Now, in relation to the Royal North Shore Hospital, did you provide Dr Neiron with an opportunity to look at the patient files as you've described them at that hospital?---Yes, I did.

10 And should we understand your description of the hospital, of the patient files in the same way that you've described them with respect to the Royal Hospital for Women?---Exactly the same.

Thank you. And when was it at Royal North Shore that you provided Dr Neiron with that opportunity to look at the files?---May, around that May period.

About the - - -?---I knew, I know that because he had another meeting with us in relation to some more marketing material.

20 All right. And whereabouts at the hospital did you and he sit and examine the patients files there?---Oh, I probably wasn't allowed to but I took him to level 8 to my desk.

So your evidence is that you took Dr Neiron to the secured area in the Kolling Institute building - - -?---That's correct.

- - - and you both there sat and examined the patient files?---That's correct.

30 And was that because that's where you kept the patient files?---That's correct.

All right. Now - - -

THE COMMISSIONER: In a drawer in the desk?---Sorry?

In a drawer in the desk?---Oh, no, there's a, there's a desk like that and it's got barriers on the side and there's a shelf and they were kept on that shelf.

40 MR ALEXIS: Now, Ms Lazarus, just going back to your evidence a moment ago about the patient list - - -?---Yes.

- - - that you say was available to you at the Royal Hospital for Women - - -?---Yes.

- - - and I put to you that it was the list concerning the patients of Professor Hacker and Associate Professor Marsden and you responded, I think, by telling me that it was the general list. Now, what - - -?---It was the daily list.

- - - do you mean by the general list?---It was the daily patient list, outpatient list for that clinic.

THE COMMISSIONER: Where did you get it from?---The what I was calling the nurses' station and what they're referring to as the reception area. There isn't just one receptionist there, there are four there and there are three other, as you enter there are three other offices there that other nurses site, well, I'm calling them nurses but they could be receptionists or whatever
10 she's referring to but I refer to them as nurses. As the reception area is here and you walk in and there's a waiting room here, as she's drawn it - - -

On the right, as you walk in there's a waiting room on the right?---That's correct, that's correct. And, and on the left next to the nurses' station there are two more, two, two, two more doors and another corridor leading outwards. I'm not sure if I should call them nurses or receptionists, I think I should call them nurses because they, they are more of a nursing role.

But they're not the ones at the reception desk?---They are the ones at the
20 reception desk but in total there are about four, five ladies running around.

At the reception desk?---At the reception desk. There isn't, I've never, like I said in my previous statement as well, I have never seen Emma at that desk ever in my life at that desk, never, that person that claims - - -

So where did you, you were asked where did you get the patient list?
---From that reception desk.

How did you get it?---She knows I was - - -
30

Who's she?---Whoever the rotation reception was. I asked her. I said, Can I please have today's um, um, um, patient list, as I've done in every single hospital.

But how did you know which patient?---Oh, then I walk up to the patient and I go, Hi, we're just conducting, because I would have that eight, eight page information thing I would go up to the patient and go, Hi, we're conducting a clinical trial and this clinical trial involves patients with abnormal Pap smear, I was wondering if you would want, like I had a whole
40 script read out, it would be, and then I would go through page by page, they'd say yes, I'll leave that information thing with them and a pen and I will walk away and try and recruit while still screening up and down. I always had that room and there's a room on the other side where she said there's a storage, the storeroom is there and there's another room here that's always free and in front there was another professor that I was telling you about that I had a conversation with and I actually gave him material to read on one occasion. That room is always free most of the time. It's occupied

as well, when it's occupied then all the rooms are occupied then I have no room so I can't - - -

THE COMMISSIONER: Is that Professor Campion?---I don't know his name.

Dr Campion?---I have no idea, like I was saying, I have, I don't know his name.

10 MR ALEXIS: Ms Lazarus the patient list contains what information about
the patient?---The patient name, the date of birth, other personal details like
address and things like that. Sometimes, it depends if the patient has some
results available, some files they have to accompany, sometimes they have a
list of like radiology film or not picked up or must pick up, like, do you
know what I mean? General information on the side. Based on that you,
you can determine which patient is coming in for what, it's not just that a
nurse needs to hand you that or anything like that. For example, I'm just
going back as an example because you have that in front of you, in the rest
there you can see the patient's got, it's FN on it, fine needle procedure or a
20 biopsy procedure, you can see which patients, which and what they're
coming for. If a patient has had a fine needle and they're waiting for results
I can't screen that patient so I'm able to determine that patient cannot be
screened. If a patient's already had a scraping for her cervix I cannot screen
that patient and it would be outlined that they're waiting for these results on
that patient list. So that's how I can determine that a patient can be
included on the trial and cannot be included and has to be excluded from the
trial and that's with prostrate patients as well. If they're waiting for a
biopsy or they've got the PSA test results available or they're normal I
cannot have a patient before, I have to have a patient before the biopsy. I
30 cannot have a patient after the biopsy and that's outlined - - -

Ms Lazarus, is your evidence that you procured what you've described as
the general patient list for the clinic at the Royal Hospital for Women?---
Yes, that's correct.

Based on the information contained in that appointment list for the day - -
-?---Yes.

40 - - - you were able to identify patients that might be suitable for the clinical
trial involving the device?---Yes, that's correct.

And is your evidence that you were able to make that determination without
any other information apart from what was contained in the patient list?
---That's correct. And the brief interview with the patient.

All right. So your evidence is that there was no involvement of either Nurse
Barlow or Nurse Knowland in the identification of patients that might be
regarded as suitable for the use of the device as part of any clinical trial?

---That's correct. I've been saying that since day one.

Well you might have been, but I'm just seeking to get it clear with you?---
Sorry, that's just - - -

Thank you. Is what I've just put to you absolutely correct as far as you're
concerned?---100 per cent correct.

10 In other words Nurse Barlow and Nurse Knowland you regarded as being
completely and utterly irrelevant to the identification process of patients
upon you, upon whom you conducted the examination using the device. Is
that right?---For the known positive, the 100 per cent positive as the control
positive, yes, I would have, I did recruit the patients that she pointed out to
me, because they were relevant to the trial as known positives. And they
can be used as a control group. For that yes, definitely she was required.
But for other patients no, they weren't, they weren't required. I didn't have
a nurse at any other hospital who pointed out patients to me.

20 All right. Now in so far as the patients on the general list are concerned - - -
?---Yes.

- - - were the patients who were on the list because they were there to be
consulted by Professor Hacker and Associate Professor Marsden?---Yes.

And were they there for the purpose of being consulted by any other doctor
at the Royal Hospital for Women?---Yes, they were.

30 How do you know that?---Because it was the full daily list and Hacker and
Marsden are not the only ones (not transcribable) utilising those rooms. I'm
aware of that.

So are you aware of any examination being conducted on any patient of a
doctor at the clinic other than the patient of Professor Hacker and Associate
Professor Marsden?---Yes.

And did you speak to any other doctor whose patient that was in order to get
their permission before conducting an examination?---No, that was my
error.

40 What do you mean that was your error?---In that I should have gained their
permission and asked them to be part of the clinical trial before (not
transcribable)

THE COMMISSIONER: Did you, are you saying that you went on any day
of the week or did you go there only on particular days?---No. I went,
because there were other trials running at the same time, I was a bit
stretched. For that reason I, I went on other days as well. And for that - - -

Other days then what?---Other days then Tuesdays and Thursdays. They had a larger patient pool apart from Tuesdays and Thursdays. Mondays were the, I would say the best days.

But Professor Hacker was your supervising professor wasn't he?---Yes, yes. Who told me I can utilise patients from that clinic. And that's what I was doing.

10 He told you you could come on other days?---Well he, he instructed Tuesdays and Thursdays, but there were more patients on other days for the general pool, for the 200 patients, which he was aware of.

Yes, but does that mean that you ignored his instruction and went on other days?---No, no, no. Because he doesn't, like he mentioned to you, he doesn't have patients that have abnormal pap smears. In the protocol it clearly outlines, which he is aware of because I emailed it to him. It says there, 200 patients, 100, 10 patients.

20 You're not answering my question?---Yes.

I'm asking you - - -?---No, I did not disregard his instructions.

But you went on other days?---Yes. To procure the - - -

But I thought his instructions were to go on Tuesdays and Thursdays?---For the pilot study, not for the, not for the 200 patients.

30 Did you tell Professor Hacker that you were going on other days to get patients from the general pool?---Yes. And he said it was fine. And not only that I was sitting at that desk not just sitting there staring into thin air like mentioned by Emma, I was sitting at the desk. I was just wondering what I was doing. I was actually putting these files together. And that's why I couldn't go to lunch.

MR ALEXIS: Ms Lazarus, I need to in the remaining time this afternoon turn some attention to Professor Burton and Dr Valdermere. You told us earlier that you conducted a number of trials using the Medex device on patients of Dr, of Professor Burton. Do you remember that?---Yes.

40 And you told us that that preceded the letter that you provided upon him to sign of May, 2009. Do you remember that?---Yes. Yes.

Now can you tell me please how it was that patients that were suitable for testing were identified before you examined them and let's be clear with one another, I'm talking of the patients of Professor Burton at Royal North Shore?---I only saw Professor Burton's patients, I didn't see Sue Valdermere - - -

You've told us earlier that you saw Professor Burton's patients - - -?
---That's correct, yes.

- - - only, you never saw Dr Valdermere's patients?---No, none of hers.

But could you attend to my question. How did you identify Professor
Burton's patients as being suitable for examination with the Medex device?
---Exactly the same way.

10 Well you'll need to explain that to me?---Oh, okay. His receptionist has a
patient list (not transcribable). He would see, he would, he would see me
doing this because his room and the waiting room and the reception area and
the spare room that was utilised by me, are right next to each other. To
complete those 10 patients, but these had to be particular patients. They
couldn't just be those 200 random patients. I had to look for certain patients
and actually have a talk with them and make sure they're the correct patients
according to the protocol that was lined out for the pilot study.

20 So tell me where did this occur with respect to Professor Burton's patients?
---In his office area where his patient, his office is here, like that door. The
reception area is here, the main door is, the entrance is there and the waiting
room is just there. So in this, in that much area you will be at his, his office
is here, the spare office is just there, the reception is there and the waiting
room is right there. He would see me. He would know what I'm doing.

All right?---The 10 patients that was seen.

30 And just in terms of the list of patients for the day, did you obtain a list from
his receptionist or a nurse?---Yes. That had, that had to be sorted.

Well who did you get the list from?---From the receptionist.

What information was on the list?---Similar information, just the details of
the patient.

What sort of details?---Date of birth, it's always exactly the same 'cause
they all use the same programme to print off all of these.

40 But what information was available from the list to identify whether or not
the patient was suitable?---A slight description of what the patient results or
what they were waiting for. Based on what they were waiting for, what
procedure they were going to go in for I was able to see because he's an
obstetrician as well. He had, he had women who were expecting and
obviously you can't carry out the Medex test on them. The majority of the
patients of his were women who were expecting. But there will be his
patients as well that you could analyse.

All right?---So I couldn't do what I did with the, the Women's Hospital, the Strathfield Hospital, in terms of the large number, be able to complete a certain number of patients within that few hours. This had to be screened a little bit more finely.

10 All right. So he, on your evidence left it to you to identify from the patient list for the day those that you would speak with and procure for examination with your clinical trial. Is that what you're saying?---That's correct. And at which point, to make it actually easier for the, 'cause I know they're busy, there is another folder, another booklet in my, in that bag where I actually go to the trouble of putting together like a, what on the graph, if a person had positive breast cancer or symptoms of breast cancer would look like on the Medex graph, basically translated the algorithm into graphical form so they're able to read the graph in five seconds rather than sit there scratching their head for an hour. And there's an example of that in there and exactly the same thing, the same folder, the same information, everything is contained for the other two hospitals as well.

20 MR ALEXIS: Now, in relation to Professor Burton's patients, I gather in the same fashion as you've described you would retain a patient file?
---That's right.

That is to say a patient file that contains the consent form- - -?---That's correct.

30 - - -and the other material that we described in some detail a short while ago as illustrated by the files from the Strathfield Breast Clinic. Is that right?
---That's correct. And all the patient consent form need to be on letterheads. That's why I had letterhead, 'cause that's the protocol for ethics. All the consent forms are all on original letterheads.

And in relation to Professor Burton's patients I gather at a convenient time between you, you showed him your patient files?---That's right.

And you showed him the printout from the computer in relation to the examination of the patient?---That's right, so he can circle if it's a negative or a positive and sign off exactly the same way.

40 And do you say that he actually did that?---Yes. That's what he worked that report and okayed that report.

And on how many patients are we speaking of with respect to Professor Burton looking at the results produced after the examination, signing off whether it's positive or negative and looking at the associated graph?
---Exact ten.

How many?

COMMISSIONER: I beg your pardon?---Ten.

Ten?---Ten. Gil Burton's- - -

Only ten?---Only ten, just for the pilot for the purpose of that report.

So you didn't see more, during the whole period you didn't see more than ten patients- - -?---I saw more- - -

10 - - -of Dr Burton?---No. I saw about, a little bit more but for the purpose, I only showed him ten because that's what he wanted, ten.

Ah hmm?---There was no need to show him more, but I didn't exceed 20.

MR ALEXIS: Now, Ms Lazarus, you've been here for a while now. I just want to conclude if I may some questions concerning Dr Vaux because of his availability tomorrow?---Yes.

20 Now, in relation to Dr Vaux's patients, I think your evidence was that you saw and examined at least 200 of his patients. Is that right?---That's correct.

And we get that I think from the letter that he signed on your evidence in about June of 2009?---That's correct.

And we should understand that by the time he came to sign that letter you'd examined at least 200 of his patients- - -?---That's correct.

- - -who were prostate cancer patients?---Yes, but before biopsy.

30 Thank you. Now, can you tell me please what information you had made available to you for the purpose of identifying his patients and whether they were suitable for testing with the Medex device?---Um, when I met him, after I met him quite a few times in the cafeteria, on one occasion he did take me up to the clinic and he showed me um, where I can um, recruit these patients from. Um, and that's exactly where I went. And um, I followed exactly the same way, getting the patient list.

THE COMMISSIONER: And who gave you the patient, his patient list?
---Reception desk.

40

MR ALEXIS: Reception where?---In, in, in- - -

Within the Royal North Shore Hospital?---In the Royal North Shore Hospital.

Yeah, but whereabouts?---Level 4.

Level 4 of what building?---The main hospital.

The public hospital or the private?---He doesn't sit in the private.

All right. Thank you. So Level 4 of the public hospital- -?---That's correct.

- - -you were provided by a receptionist, is that right?---That's correct.

10 With his patient list for the day?---That patient list for that clinic for the day.

For his urology clinic?---For that urology clinic. There were other urologists in there as well.

All right. And what information was contained in the patient list that you were provided with?---Um, most, again name, date of birth um, other personal details. Um that clinic um, mainly had um, patients who were undergoing a biopsy procedure and um, I had to recruit them before they went for a biopsy um, prostate biopsy and um, otherwise I wouldn't be able to screen those patients. We, I also screened general patients who had just
20 abnormal um, PSA um, as outlined in the protocol exactly. Um, that's why for the purpose of the um, the letter, it says 200 patients but when I completed the analysis, 48 patients before biopsy. That's what the letter outlines and that's what he's approved. But for the tests that were conducted, again I printed out exactly the same graph um- - -

Well, before we get to that- -?---Yeah.

- - -I'm still with the patient list, if you don't mind?---No.

30 What was it on the patient list in respect of Dr Vaux's patients that told you whether they were pre or post biopsy?---Um, that's the reason why they were there, the patients that were there.

Well, how did you know that?---Oh, that's the biopsy clinic.

So you proceeded on the basis that every patient attending was there for biopsy?---Yes, and a small interview from the patient, yes.

40 And does it follow that therefore they were all pre-biopsy?---Yes.

All right?---And also there were other patients that had abnormal PSA's as well (not transcribable)

THE COMMISSIONER: Were you concerned whether, whether the particular patients had had cancer for some time or whether this was pre, there for pre-cancerous investigation?---They were all there, they were all there for, these patients were all there for, to um, for an examination to determine what they have. The biopsy will determine whether they have

cancer or not. Um, there is no, they're not cancer patients, you can't say they're cancer patients as yet, but these patients who were there biopsies had abnormal PSA result, that's why they're there for a biopsy to determine um, what level of disorder they have.

MR ALEXIS: And so, Ms Lazarus, after examining patients that you identified from the list that you were given by the receptionist, should we understand that you adopted the same procedure with respect to the maintenance of the consent form and the other documents that you've described- - -?---Yes.

- - -by reference to the Strathfield Breast Clinic material?---Exactly the same.

All right?---Exactly the same graph sample was drawn up and I met Vaux in um, in the cafeteria with the sample because I know he was really busy, so I drew up the sample to indicate what's positive and what's negative and the graph was shown to him and he completed exactly the same form for the (not transcribable) patient, I had to do it in lots because- - -

And when you say exactly the same form, you mean the form that he signed off on indicating whether - - -?---The same - - -

- - - or not the result of the test was either positive or negative?---That's correct.

And he did that in association with the colour pictorial graph illustrating the results of the test?---That's correct.

So we should understand that after examining the patients identified from his list - - -?---That's correct.

- - - you then took to him that paperwork with the results and he signed off to indicate whether it was a positive or negative result?---That's correct.

Is that right?---That's correct, I never took the folder, the white folder to him in the cafeteria. I took 50 lots or 30 lots or whatever I had completed when he was available of just the coloured graphs, a sample that I had created and on a letterhead whether it's a positive or a negative, you can circle, a bundle of those so in total I took three sets of documents. I placed the sample graph in front of him. The remainder of the graphs there allowed him to complete that, that form.

And after you'd gone through that exercise with him you filed that paperwork in the plastic sleeves in the white folders and they were stored in your drawer on level 8 at Kolling?---No, on the shelf, on the shelf.

I'm sorry?---On the shelf on top of my desk.

That was, we're back in the Kolling Institute building on level 8, is that right?---The Kolling (not transcribable) that's correct.

By the way, the two folders from Strathfield, you may or may not know the answer to this, how many examinations do those two folders contain the results of?---201 samples.

10 So with respect to the tests on Dr Vaux's patients there would have at least been two similar full folders of paperwork relating to those examinations?
---That's correct.

All right. Yes, thank you, Ms Lazarus. Commissioner, I see the time. By reference to the excursion into the Strathfield material I haven't completed but I'm very close to it but I, I certainly - - -

THE COMMISSIONER: Continue with Ms Lazarus (not transcribable)

20 MR ALEXIS: Yes. What I was going to indicate is that I'm in a position having understood the evidence this afternoon to deal with Dr Vaux in the morning who I understand has limited unavailability which, has limited availability which is why I dealt with what I did.

THE COMMISSIONER: I understand.

MR ALEXIS: And similarly Professor Burton so we can proceed with him tomorrow.

30 THE COMMISSIONER: Yes.

MR ALEXIS: Now, Commissioner, before we adjourn I understand my friend has an application.

40 MS SOARS: Commissioner, it's just that my client was asked questions earlier this afternoon about the date of a meeting between Gil Burton and herself and Vern Pleiksna, a Vern David Pleiksna and at some point she, she did agree according to my maths it was, it was October 2009 but she said she would need reference to the travel arrangement details in order to confirm that. I have a email from Vernon David Pleiksna to Sandra Lazarus attaching their flight itinerary with their travel arrangement details which I would seek to show her and just get her to then confirm that evidence or not as the case may be.

THE COMMISSIONER: You have that leave.

MS SOARS: I only have one copy. I apologise, Commissioner, I'm, I'm told - - -

THE COMMISSIONER: I don't think you need, you don't need to do it now.

MS SOARS: It's just it may affect Gil Burton's evidence I would imagine, well, what may be put to Gil Burton. That's why I'm doing it now, Commissioner.

THE COMMISSIONER: Well, I think that if you give Mr Alexis - - -

10 MS SOARS: He, he has a copy, I'm sorry, Commissioner.

THE COMMISSIONER: Well, he will know, he'll be, he'll be able to deal with it I imagine.

MS SOARS: All right.

THE COMMISSIONER: Did I understand this correctly, you now want to ask, do you want to ask Ms Lazarus some questions based on those documents?

20

MS SOARS: I do.

THE COMMISSIONER: Now?

MS SOARS: Well, I was just suggesting that we just clarify this point before - - -

THE COMMISSIONER: All right. Well, what's your attitude, Mr Alexis?

30 MR ALEXIS: I have no objection.

THE COMMISSIONER: Yes, proceed.

MS SOARS: Could I show you this document which is an email dated 14 May, 2009 from Vern, Medex Test Corp to yourself with an attached flight itinerary. Do you recall that earlier today Mr Alexis asked you some questions about the date on which you went with Vernon David Pleiksna in Sydney?---Yes, that's correct.

40 And do you recall that he put to you that the meeting was in October 2009 and you answered, Correct?---Yes, that's correct but then I right away said I wasn't sure but flight details would be able to confirm the date.

By reference to the document I've given you, which is a flight itinerary, do you have anything further to say about that?---Oh, it's May, the flight itinerary shows May.

And in relation to the meeting what impact does it have on the date of the meeting? What was the date of the meeting?---Around, between May 6 and May 8.

2009?---2009.

And it wasn't October 2009?---It wasn't October 2009 (not transcribable).

That's all, Commissioner.

10

THE COMMISSIONER: So are you, are you saying that Mr Pleiksna only came once to Sydney?---That's, no, once to, he came to Sydney I don't know how many times but this, and he will be able to confirm that because there, I took them to every hospital. I was their chauffeur for the day.

MS SOARS: I don't think that's the question?---Oh, okay. I didn't understand.

It's just about the date of that meeting?---Yes, okay.

20

THE COMMISSIONER: I'm trying to find out whether they came to Sydney on more than one occasion and whether that email is a reliable indication of the date of the meeting?---But that's a reliable indication of the date of the meeting.

Why?---Because it's the only time I saw them and the only reason why they had to send me an email.

So did you only see them once in Sydney?---Only once in Sydney.

30

MS SOARS: Commissioner, I might indicate the email also refers to meetings with Professors Sue Valment, which is a typo, Gil Burton et cetera so in my submission it's the same meeting.

THE COMMISSIONER: I understand. All right. We will adjourn. I take it, can we adjourn 'til 10.00 or do we need, we'll adjourn 'til 10.00am tomorrow.

40 **THE WITNESS STOOD DOWN**

[4.44pm]

AT 4.44pm THE MATTER WAS ADJOURNED ACCORDINGLY

[4.44pm]