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INDEPENDENT COMMISSION AGAINST CORRUPTION

THE HONOURABLE DAVID IPP AO QC

PUBLIC HEARING

OPERATION CHARITY

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TRANSCRIPT OF PROCEEDINGS

AT SYDNEY

ON WEDNESDAY 16 FEBRUARY 2011

AT 9.45AM

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THE COMMISSIONER: Mr Alexis.

MR ALEXIS: Thank you, Commissioner. Before we start that there are further appearances this morning.

THE COMMISSIONER: Yes.

MR LYNCH: Commissioner, if you please, my name is Lynch, I appear with Ms Furness for New South Wales Health (not transcribable)

10

THE COMMISSIONER: Yes, Mr Lynch, thank you. Anyone else?

MR ALEXIS: Apparently not, Commissioner. Well not yet anyway. Commissioner, I seek to call Ellen Louise Barlow.

THE COMMISSIONER: Yes, Ms Barlow. Mr Lynch, is Ms Furness, I don't her here, she's not here today is she?

MR LYNCH: Well, she may be some time later in the day.

20

THE COMMISSIONER: And I take it you wish me to make a section 38 order.

MR LYNCH: I would, I do, absolutely.

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

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

Now Ms Barlow, do you wish to give your evidence under oath or do you wish to affirm the truth of your evidence?

MS BARLOW: Under oath.

THE COMMISSIONER: Would you swear Ms Barlow in please.

<ELLEN LOUISE BARLOW, sworn

[9.45am]

THE COMMISSIONER: Mr Alexis.

MR ALEXIS: Thank you, Commissioner. Madam, is your full name Ellen Louise Barlow?---It is.

10 You are currently employed as a clinical nurse specialist by the South Eastern Sydney Illawarra Area Health Service. Is that correct?---That's correct.

And you work at the Royal Hospital for Women?---I do.

And is it the case that you provided a statement of evidence to ICAC investigators on 2 July, 2010?---I did.

Could I provide you with a copy of your statement with a copy for you, Commissioner.

20 THE COMMISSIONER: Thank you.

MR ALEXIS: And Ms Barlow, is that the statement to which I have just referred?---It is.

And the content of that statement is true and correct to the best of your ability. Is that right?---Yes, it is.

Thank you. And I tender that statement, Commissioner.

30 THE COMMISSIONER: Yes. The statement of Ms Barlow will be Exhibit 11.

#EXHIBIT 11 - STATEMENT OF MS ELLEN BARLOW

MR ALEXIS: Now Ms Barlow you tell us about your experience and years of service as a nurse in paragraph 3. Is that so?---Yes, it is.

40 You've been a nurse for 30 years?---I have.

And should we understand your particular role at the Royal Hospital for Women to co-ordinate gynaecological oncology outpatients for Professor Neville Hacker, the director of the Oncology Centre?---Yes, I do. I've also got a dual role, I work as a research nurse for Professor Hacker as well.

Thank you. And in that regard are you someone that is involved (not transcribable) with the making of applications to the Human Research Ethics Committee?--I am, yes, for Professor Hacker.

Thank you. And does your role also include the collection of research data in relation to the performance of trials?--It does to an extent, yes. I, I collect data, I actually get data from files for survival and morbidity statistics, things like that. I, if there's a research project going on I don't collect the data, it's up to the individual who's actually doing project.

10

All right. Now on the subject of Ethics Committee applications, in 2007 and 2008 did you have an understanding about the process involved in obtaining ethical approval?--Yes.

And could you tell us a little about that understanding?--The, the person who's initiated the research will fill out an ethics application online, it's a national online form now. And we submit it to the Area Ethics, Lead Area Ethics within the Area Health Service that you're in. So for, for us at the Royal Hospital for Women it is the Northern Network Area Health Service and that's the lead centre is based at Royal Prince Alfred Hospital. And then you need to add into that document a site specific assessment form which would be for Royal Hospital for Women, which would go to the on site at the Prince of Wales Hospital, yeah, which is the site, for the site specific assessment. That's all one document. It's one big document. The site specific assessment is at the end of that. Is that what you wanted?

20

Yes. And what during those years was your understanding about whether or not a clinical trial, the subject of such an application could proceed without ethical approval having been granted?--I was not aware that ethical approval had not been granted and a research study would never be, would proceed without ethics approval.

30

Now paragraph 17, again just on the subject of ethic approval, you tell us that you've assisted people with those applications and then you made reference to Ms Sandra Lazarus. Did you ever see or were you in any way involved in any application made for ethical approval with respect to the use of a Medex device on patients at the Gynaecological Oncology Centre at Royal Women's Hospital?--I was aware of the proposed study but I was never involved in the ethics application.

40

So the Commissioner should understand that you never saw it - - ?--No, I never saw it.

- - - either in draft or in final form?--No.

And your evidence in paragraph 17 is that you were never asked for assistance by her with respect to the completion of that application?--No.

Is that so?---No, and that's not unusual.

Now, could I come to some events that you tell us about in paragraph 6 and following of your statement. You tell us that in 2007 you recall attending a presentation that Ms Lazarus provided at what you there describe as a Thursday lunchtime meeting. Do you see that?---(NO AUDIBLE REPLY)

10 Now, can you recall during that presentation whether Ms Lazarus spoke at all of having conducted clinical trials using the Medex device at any other hospital?---I have a memory that she talked of it at St Vincent's Hospital but I wouldn't be absolutely certain on that.

All right. And does your memory allow you to indicate whether or not she conveyed to those assembled at the lunchtime meeting whether she was involved at that point in time in any studies at any particular university?---I came away with the impression that she was a PhD student, she was doing her PhD. That I, I indicated I thought at New South Wales University but others have said they, they, their impression was Sydney University.

20 Well, leave aside which particular university, you had the impression that she was - - -?---She was acting, she was a PhD student and this project was part of that.

And what led to you leaving that meeting with that impression?---It was something she said at the meeting.

I see. Thank you. Now, in paragraph 7 you tell us that following that presentation Professor Hacker spoke about the prospect of a pilot study which involved yourself and Emma Knowland. Do you see that in
30 paragraph 7?---(NO AUDIBLE REPLY)

And who should we understand Emma Knowland to be?---She's the other nurse in the, works in the outpatients department. She covers some of the other consultants and also covers the pre-invasive clinic.

Thank you. And you see that in paragraph 7 you refer to what Professor Hacker indicated as to the criteria for referral of new patients. Do you see that?---Ah hmm.

40 Could you, could you just explain what it was that Professor Hacker informed you about as to who the prospective patients might be that could be involved in such a study?---My memory of it is that it was all new patients with a positive diagnosis of a cervical cancer, early stage cervical cancer and also some high grade abnormalities, pre-invasive cancers of the cervix but it was absolutely entirely cervical cancer and early stage.

THE COMMISSIONER: Sorry, Mr Alexis.

MR ALEXIS: Yes, Commissioner.

THE COMMISSIONER: What makes, why would you and Nurse Knowland be in the best position to make referrals to the trial?---We wouldn't be making referrals as such, I guess it's a play on, a bit of a word, a different word. We identify eligible patients from the list of patients that are coming to a particular clinic, Tuesdays and Thursdays are the gynae oncology clinics and we could look down the list, we know all our patients, we know what their diagnosis is so we can identify them by looking down a
10 list and, and checking the file and saying well, this lady is presenting as a new patients with a high grade abnormality or a proven diagnosis of a cervical cancer.

And which file, which file is it that you would be checking?---There's a, there'd be a new file generated for new patients, it's a clinic outpatient file. They're kept in the compactus behind Professor Hacker's secretary in the main office.

And who has access to that?---We do, the nurses have access to them, the
20 secretaries and the consultants in the department.

Anyone else?---Realistically I suppose they do, they're not locked all the time, the office is locked when it's left but (not transcribable).

Who's authorised, who, is anyone else authorised to have access to them?--- Within the department they are, yeah. You can

Who?---Because we have to access it. A patient will ring with a, who's had surgery um, will ring with a problem and you have to go and be able to
30 access the file and see, you know, go through the history.

So are you saying that anyone in the department is entitled to go to the file?
---Yes.

But who, now, I'm not sure if I understand why only you and Ms Knowland would be in a position to make referrals?---Because it's part of our role within the outpatients' department. We're the two designated nurses that do this. We identify patients for a routine number of research studies because we're there onsite and we, it's just part of our role. No one else would- -
40

I see. No one else would what?---No one else would know the patients well enough, they don't understand, none of the secretarial staff understand a lot of the, a lot of the results that come through. A secretary would not pick up a result and, and think, oh, this woman would be eligible for this study. It's, it's, you need a higher level of knowledge.

Right. And is there anyone else who could do, who could identify the patients then, other than you and Ms Knowland?---There would be other, other nurses that were capable of doing it.

In the department?---In the department. But um, they, they simply wouldn't do that, it's not part of their role. Everyone's very busy, everyone has very designated roles. It would be inappropriate and it would be questioned.

Yes, thank you.

10

MR ALEXIS: Now, Ms Barlow, was the discussion that you refer to in paragraph 7 involving Professor Hacker one that occurred reasonably shortly after the presentation that Ms Lazarus gave to the lunchtime meeting or should we understand it to have been a discussion that occurred some weeks or indeed months later?---My memory of it is that it occurred after Ms Lazarus presented her, made her presentation- - -

Mmm. Mmm. All right---?- - -at that meeting.

20

THE COMMISSIONER: So it was the same day as the meeting but after the meeting?---After, after she presented. I, I- - -

That day?---Yes. Usually that's what will happen. People will present their, their research and then there will be a general discussion about whether it's relevant and then who can help them access- - -

Yes.

30

MR ALEXIS: Now, in paragraph 8 you've referred to Ms Lazarus being told something by Professor Hacker concerning the days of operation of the clinic. Do you see that?---Yes, I do.

And can you tell us how it is that you were aware that Ms Lazarus was informed about the operation days of the clinic by Professor Hacker? ---My memory that that was said at this meeting.

40

I see. All right. Thank you. And then if we can come down to the subject of you identifying patients, and you'll see in paragraph 8 you tell us that you identified a patient that was appropriate for referral and you would provide Ms Lazarus with the patient's name et cetera. Do you see that?---Yeah.

Now, I'm just asking you a question about timing?---Ah hmm.

Can recall to mind when, relative to the lunchtime meeting, you first went through the process of identifying a suitable patient, having regard to the criteria, and actually providing that patient's details to Ms Lazarus for the purpose of her then speaking to that patient?---It was a long time later. It was in 2008 and certainly in the second half of 2008. I can't be accurate at

all on any dates, but carefully thinking about it I've been able to determine that it was around August/September of 2008.

And how have you been able to determine that?---I was able to link it with, I also put in my own ethics application for a Masters Honours thesis in 2008 and I had a lot of problems with it and I can remember having a conversation with Sandra about that and it would have been towards the end of the year because I got the acceptance back in November, so it would have been at least September.

10

One further question- -?---August or September.

Thank you. One further question about the lunchtime meeting if I may. When that occurred did you have an understanding about whether or not the ethics application for the proposed trial using the Medex device had been submitted by Ms Lazarus?---From that meeting?

At the time of that meeting, did you understand that the ethics application had been submitted?---No.

20

Your understanding about that came later did it?---Yes.

All right. So what you tell us in paragraph 8 about identifying and referring patients occurred, I think you said, about the August/September period of 2008. Is that right?---Yes.

And can you tell us how it was that you conveyed to Ms Lazarus the details of a patient and what happened after you doing that?---We have a clinic list printed out and I would go through the files if I didn't recognise the patient. And just highlight, generally what I would do, would be highlight a name and then just tell the researcher. So I would have told Sandra Lazarus that this lady was coming and, and she could be approached for the study, she was eligible based on the criteria.

30

And that would occur if Ms Lazarus was present in the Oncology Clinic. Is that right?---Yes.

And, and on those occasions when she was present, did you observe her do anything in relation to the patient that you identified on the list?---I, I have a memory that she saw, seen one patient go into a room. We, we struggled for space for researchers and I'd determined that afternoon that the Lletz room, which is a procedure room wasn't being used and that Ms Lazarus could use that room. I have a memory of her taking a, a female patient into that room.

40

And does your recollection allow you to indicate where it was that Ms Lazarus spoke to that particular patient you're referring to?---It doesn't actually. Routinely it would be, I'd either initiate an introduction or I'd

allow the researcher to, to approach the patient once we've indicated that they could be approached. And that would be in the waiting room.

Thank you. In initiating the introduction or allowing Ms Lazarus to approach and converse with the patient, was there any particular place in the Centre where that occurred?---In the corridor, in the outpatient, between the rooms or we'd take them into the Lletz room and do that. But I didn't do that on this occasion, no.

10 All right. Now in paragraph 9 you tell us that Ms Lazarus attended the outpatient clinic on at least two occasions?---Ah hmm.

You go on to say that you did see her around the unit more often than that and then you tell us that despite attending the unit regularly she did not seem to attend the clinic as regularly, which meant there was less opportunity. Do you recall any occasions where you had identified a suitable patient or patients and Ms Lazarus wasn't to be seen in the Centre and you took some step to try and make some communication with her?

20 ---Yes. We, I, I rang her, I had a mobile contact number for her. But I wasn't successful in getting in touch with her. And I, I can't remember if there was, there was no ability to leave a message, I do know that. I don't know whether it rang out or whether she didn't have a voicemail. I just don't remember. But I didn't ever leave a message on her phone.

Thank you. In paragraph 13 of your affidavit you tell us that you tried to contact her a few times on her mobile and does that accurately reflect the number of times, a few times, perhaps a handful. Is that right?---It wouldn't have been a handful. It would have been three times.

30 Thank you. Now just coming back to paragraph 9. The two occasions you refer to, are you able to indicate when as a matter of timing those two occasions occurred?---Do you mean month of the year?

Yes?---Well certainly it would have been August/September as I've said before.

That's the 2008 year?---Yes.

40 Now in paragraph 10 you recall to mind a specific patient, the name of whom you provided to Ms Lazarus. Can you tell us about that occasion?

---Sorry, what do you want, what do you want to know about - - -

At paragraph 10, if you could look at paragraph 10, please. You tell us that you recall that one of the patients whose name I provided to her agreed to participate in the trial and you then tell us that that patient was seen et cetera?---Oh, okay.

Could you tell us precisely what you saw?---My memory is seeing her going to the Lletz room, that's the room I described to you before, the procedure room which was vacant on that afternoon. I did, I saw her take the woman in, I didn't see any more but I did comment to Sandra after how had it gone and she said well and that was the, the sum total of my conversation about that.

And is your best recollection that that occurred in the same period we've discussed, August/September, 2008?---Yes.

10

Paragraph 11 to advert to a second occasion where you provided patient information to Ms Lazarus and is it the case that in respect of that occasion you're not sure whether Ms Lazarus actually saw the patient and performed any test or not?---No, I'm not sure.

THE COMMISSIONER: Ms Barlow, what is the, what is the unit?---It's the - - -

20 There's a reference in your statement to a unit. Can you, what is a unit?
---The unit I'm referring to is the gynae oncology outpatient unit. It's a - - -

What's the difference between the outpatient clinic and the outpatient unit?
---I guess I'm including the outside desk, the main reception desk as well and the waiting room, we consider it the whole unit. We work as a unit.

So if you could just come back to 9 where you say you saw Ms Lazarus around at the unit more often than the time she attended the clinic - - -?
---Oh, actually, no - - -

30 - - - I don't quite understand that?---The unit I mean is the whole gynae oncology unit, including the offices, the consultant offices, my office is up in the, where the secretaries are, that's the unit, sorry.

So when you saw her - - -?---Ah hmm.

- - - around the unit - - -?---Mmm.

40 - - - but not in the outpatient clinic where is it that you would see her?---In the office, in the office outside Professor Hacker, where all the consultant's offices are there's a central administrative area. I saw her on several occasions in there.

In the, in the - - -?---In the office.

That's the office outside his rooms?---Yes.

And who, who, who's on duty in that officer?---There's two, two secretaries.

And what was she doing there when you saw her?---A couple of occasions sitting at the desk, there was a, there's a spare desk, there's facility for a third receptionist, just sitting at a desk.

Right.

10 MR ALEXIS: Now, the area that you've referred to just a moment ago where you saw Ms Lazarus sitting at a desk, is that the area outside of both Professor Hacker and Associate Professor Marsden's consulting rooms?
---Yes.

And is that the area that you've referred to in paragraph 8 of your statement and perhaps in other areas as the waiting room?---No.

So how, where is the waiting room relative to those consulting rooms?---Ah
hmm, to the left down the corridor at the end of the, the whole department.

20 All right?---And it's beside the main reception desk. There's a small waiting area and it's a waiting area only for the gynae oncology - - -

THE COMMISSIONER: So who's on duty in the waiting room?---There's a receptionist at the main desk.

And that, and there are secretarial staff in the office?---There's, at the little side there's one secretary, a little side office next to the reception desk.

30 And where, and where, and where is the place that you ordinarily work?
---Yeah, in front of the reception desk is a big, big open door and in there is four consulting rooms and a nurses' office. Directly opposite the desk.

MR ALEXIS: Ms Barlow, could I bring you through to paragraph 15 of your statement and there you provide us with an estimate of, of three patients' names that were provided to Ms Lazarus in relation to the clinical trial over the two occasions that she attended. Do you see that?---Yes, I do.

And are the two occasions you're there referring to each of the occasions referred to in paragraphs 10 and 11?---Yes.

40 And again, as a matter of timing are you able to tell us the approximate time in the 2008 year that the three patients there referred to were referred to Ms Lazarus for testing?---August/September and it was in a small period of time over two to three weeks maximum.

Now, you've told us about the two occasions in 10 and 11. How is it that you have come to estimate that three patients' names were provided as you have in paragraph 15?---My memory is that on the second occasion I provided two names, so one on the first occasion and two on the second.

And may we take it that in respect of the two names provided on the second occasions you're unable to say in relation to those two names whether in fact Ms Lazarus examined those two patients with the device or not?
---I don't know.

And now in paragraph 15 you tell us that cervical cancer is not that common, there is not a large number of patients attending the clinic that fit the referral criteria for the trial. Do you see that?---Yes, I do.

10

And was the criteria you're referring to there that which Professor Hacker spoke to you about which is set out in paragraph 7? If you can just check that, please?---Yes.

Thank you. During this period that we're speaking of, the August/September period, or indeed any time after that, did you ever see any patient consent forms, either in blank for the Medex trial or the form completed by patients that related to the conduct of any examinations that Ms Lazarus had conducted on patients?---No, I did not.

20

Did you ever see any folders, whether white in colour or any other colour, containing a plastic sleeve or a series of sleeves within which were filed documents such as patient consent forms, graphs or other information resulting from the use of the Medex device or anything like that?---No, nothing.

And could Ms Barlow be shown Exhibit 9. Ms Barlow, could I make plain with you at once that this is not suggested as a document relating to Royal Hospital for Women but I wish you to look at the colour graph I think on page 3 of that exhibit and I wish to ask you whether in the August/September 2008 period or any time after that, did you ever see any colour graphical depiction like that in Exhibit 9?---No, I've seen nothing.

30

THE COMMISSIONER: You say you've seen nothing?---I've seen nothing of this.

Have you seen any of, have you seen the results of any tests?---In relation to this study?

40

Yeah?---No, not at all.

MR ALEXIS: Thank you. That can be returned. One final matter, Ms Barlow. If you can get back in mind the lunchtime meeting that we spoke of in I think 2007 you put it, and the two occasions you refer to in your statement that occurred in the August/September 2008 period where some patients were identified and referred to Ms Lazarus, do you recall seeing Ms Lazarus either in the unit or in the waiting room or in the clinic, you appreciate I'm seeking to cover the floor, at all during the intervening

period?---I saw her in the unit before all of this on several occasions, as I've said before, but not in the outpatients and not in the waiting room.

THE COMMISSIONER: What do you mean by all of this? You said you saw her, "Before all of this?"---I saw her during the lead, after the, after the presentation and before starting to identify patients for her. She was within the department on a couple of occasions that I remember.

10 MR ALEXIS: And do you have a recollection of observing her doing anything in particular?---She had a few conversations with Helen McGilligan, just social-type conversations. I didn't stay round to listen. I had a conversation with her at one point. She offered, I talked to her about, as I said, my research. She offered to, she said she knew someone at Royal Prince Alfred that she might be able to offer me some help. I never took her up on that. That was, that was all I observed her to do on those occasions.

20 All right. Thank you. And during that period, and let me be clear, from the time of the initial presentation right through until the late 2008 period, did you ever see or were you ever introduced to her younger sister by the name of Jessica Lazarus?---No. The first I've heard of Jessica Lazarus was listening yesterday.

Yes, I see. Yes, thank you, Ms Barlow. That's all I have.

THE COMMISSIONER: Thank you, Mr Alexis. Ms Barlow, Ms Knowland is a colleague of yours who works in the clinic I understand. Is that right?---That's right. Now she's moved to Brisbane actually.

30 Right. And when she was working with you there did you work together or did you work at different times?---No, we, I, I'm part-time within the clinic, at the clinical role, she's full-time. We didn't work together, we worked alongside one another I guess, we're doing two different- -

Well, that's, what I really mean was, I'm sorry, what I really mean was, while she was there working were you there working as well?---Two days of the week I was. She was full-time, I worked Tuesdays and Thursdays in the outpatient department.

40 Right. And did, are you, did you observe Ms Knowland referring patients to Ms Lazarus?---No. No, I did not. We did discuss it though.

Yeah. While you were there, could Ms Lazarus have carried out the tests without your knowledge?---No. She couldn't have recruited the patients without my knowledge, no.

Yes, thank you. Ms Soars?

MS SOARS: Commissioner, there's been a number of evidence said on a number of matters which I feel I need to get instructions. It will only take me five to ten minutes. I asked for an adjournment to get those instructions so I can properly put some matters to Ms Barlow.

THE COMMISSIONER: Very well. We'll adjourn for, for no later than ten minutes.

MS SOARS: Ten minutes should be fine, Commissioner.

10

SHORT ADJOURNMENT

[10.18am]

MS SOARS: Ms Barlow, could you tell me about the circumstances in which you came to give your statement which is Exhibit 9 to ICAC?---I was asked to give it.

THE COMMISSIONER: Exhibit 11.

20

MS SOARS: I'm sorry, I had the wrong Exhibit number, Exhibit 11?---I was asked to by ICAC.

And then how did it come about that you made the statement? Were you interviewed?---I was interviewed in my office.

In your office. And was anyone else present?---Only the ICAC representative.

30 And were you aware of the purpose for which this statement was being obtained and the inquiry that was being made?---Yes.

And what did you understand that to be?---That Sandra Lazarus had gained money from the Royal Hospital for Women for a research project, basically. I didn't have a great understanding of it.

But you took the preparation of your statement seriously?---I did.

And it's true and correct?---Yes.

40

And you say do you that it contains all relevant conversations and information of the subject and supplemented I suppose by your oral evidence today?

MR LYNCH: Commissioner, I object to that (not transcribable) unfair. How does the witness - - -

THE COMMISSIONER: Yes. I think that's a fair comment.

MS SOARS: Are there any other conversations that you had with any person or any other matters relating to Sandra Lazarus conducting the Medex clinical trials at Royal Hospital for Women that you're aware of?

THE COMMISSIONER: That's too general (not transcribable)

MS SOARS: All right. I'll leave that, Commissioner. Since making your statement have you discussed any of the matters you've dealt with in your
10 statement with any person other than your lawyers?---I haven't talked about my statement. I've discussed the, this issue, but I haven't discussed anything that I've written in my statement to anyone.

You've discussed some of the matters that you've dealt with in the statement with people? For example, how many referrals you made to Sandra Lazarus, have you discussed that with anyone?---No, I haven't.

Not with Professor Hacker?---No.

20 Could you tell me about, you, I think at the end of the examination you said you were only part-time in Professor Hacker's clinic. Is that correct?---He only does two clinics a week, two days.

Two days?---I do his clinics.

30 And can you tell me about your responsibilities within his clinic during the period 2007 and 2008?---Yeah. I, I co-ordinate his clinic, so within, within the actual clinic process, but I follow through on all patients. I co-ordinate their surgical procedures, their tests and I follow them through the ward. I organise their post-operative care, their radiotherapy and then I follow them through their survivorship.

And are you involved in supervising staff yourself?---No, I'm not. That's not part of my role, only the, within when I'm working, I run his clinics and I will organise the administrative staff to do a few things, that sort of thing.

And do you, are you enrolled in any, sorry, involved in any education of nurses within the unit?---Yes, yes.

40 And what does that involve?---Presenting papers, doing in-services on different, I have an area of expertise vulva cancer and cervical cancer. I provide nursing staff with presentations, information, that sort of thing. I have a, another area of expertise in regards what are the outcomes of treatment and I present on that regularly.

And where would these presentations take place? Presumably not in Professor Hacker's rooms?---No, no. They were, we have a tutorial room on, in the department on level 2. They might be in the nurses' office on the ward, various places.

Various places. And you said in-service courses, does that involve outside the hospital or - - -?---I present from time to time at other areas, yeah.

So it's correct to say that during the period where you're working Tuesdays and Thursdays you're possibly not in the ward because you're attending to these other matters relating to education?---No. Tuesdays and Thursdays are my clinical days. Monday, Wednesday, Friday I do the other.

10 You do the other, you attend to the other matters, it's true to say though you have a lot of demands on your time, I mean you sound like a very busy person. Is that correct?---Yep.

And do you consider yourself to be a good record keeper? A good administrator?---I think so, yes.

And do you often keep records to assist you to remember what occurred on a certain date? Is that correct?---I don't, I'm not a very good diary person. I don't write things in diaries, no.

20

And is it possible that Professor Hacker worked longer hours than you did within his rooms on the days you were there?---No, no. I go home at the same time he does actually, generally.

And what hours were you at the clinic for on Tuesdays and Thursdays? ---My hours are around 8.00 til 6.00, 6.30. Actually, Professor Hacker leaves the clinic before I do.

30 You sound like you're hardworking. Could I, could I take you to paragraph 14 of your statement in Exhibit 11. Could you just read that to yourself, please. You were intending to convey by that paragraph that you asked Sandra to come to lunch on a number of occasions. Is that correct?---I didn't ask her, she was asked by Helen McGilligan. I'm not sure how many occasions, but a couple of times.

So - - -?---She was in the office.

- - - was she asked by Helen McGilligan in your presence?---Yes, yeah, we were going down to lunch.

40

On a number of occasions. And she declined. Did she say any, for example, I'm too busy, I can't come to lunch?---I think, yes, I mean she didn't just say no, I'm not coming, yeah.

Something along those lines?---I don't know what her words were.

Not specifically. I think it would be helpful, Mr Commissioner, if I could ask this witness to do a diagram of the set out of the rooms because there's a lot

of confusion and I would ask this witness to do a diagram of Professor Hacker's rooms, the general public outpatient area and the consulting rooms which I understand come off that area including the Lletz room.

THE COMMISSIONER: Are you able to do that?---I can do it, I'm a very bad drawer though.

10 MS SOARS: I think it would be of assistance. I have blank piece of paper for that purpose. I'm now sure how long, to be fair to Ms Barlow, that might take, whether again a short adjournment would be appropriate. I am in your hands, Commissioner.

THE COMMISSIONER: We'll see?---This is very rough, is that okay?

MS SOARS: Just whatever you can do would be of assistance.

Commissioner, it may be convenient if that document is copied a few times so that we can all have a copy when I ask her some questions about it. Thank you.

20

THE COMMISSIONER: I suggest you proceed in the meantime.

MS SOARS: Yes, I will. Can I take you to paragraph 8, 8 of your statement, please. I haven't seen the diagram, but I understand there's a general waiting room that patients come into and presumably they see a number of doctors from that waiting room. Is that correct?---Yeah.

How many doctors keep permanent rooms somewhere adjacent to that waiting room?---There's four consulting rooms.

30

Okay. But how many doctors for example have an office in that general area?---One, two, three, four, four, plus Oncology Fellows share one office.

And could you, who are those doctors?---Professor Hacker, it was Professor Marsden, he's retired, Dr Greg Robertson, Dr Rhonda Farrell, there's five, and Dr Mick Campion.

Sorry, I didn't get that. Dr Greg Robertson?---Robertson. Dr Rhonda Farrell.

40

And Campion, Dr Campion. And did they all share a specialisation in gynaecology but perhaps in different areas? Is that correct?---They're all gynaecologists except for Dr Campion is an expert in pre, he's a gynaecologist and expert in pre-invasive disease.

And do they conduct their clinics on different days?---Yes.

And could you tell me the days that, well, firstly can you tell me which doctors might for example see patients who have just an abnormal Pap smear as opposed to something else more serious at that point in time?
---Dr Campion, Dr Campion's clinic.

Campion. And what days does Dr Campion conduct his clinic?---All day Tuesday and Wednesday.

10 Thank you. And are you aware of how many patients Dr Campion sees in his clinics on a daily basis?---It would be about 15 on a daily basis, but I'm not absolutely accurate on that 'cause it's not my- - -

And are you aware of how many of those patients perhaps might have abnormal Pap smears?---No, I'm not.

20 MR ALEXIS: Commissioner, can I object to, Mr Commissioner, I don't object to the question and answer that's just been given, but if our learned friend is about to proceed with an examination of patients concerning Doctors Campion, Farrell and Robinson, and I suspect from the question that has just been asked and answered that she might be, then I would ask her to indicate what the relevance of it is in regard to her client's evidence which makes plain the patients of the particular doctors that she was concerned with.

THE COMMISSIONER: That is, I must say, that thought has been occurring to me throughout this.

30 MS SOARS: Your Honour, I think it was indicated through some questioning from Mr Stitt yesterday that, that perhaps some patients which, well, I'm instructed the patients who had just abnormal Pap smears were tested by my client and it may- - -

THE COMMISSIONER: No, that's not, no, there's no evidence to that effect.

MR SOARS: But, Mr Commissioner, we haven't had an opportunity to lead any evidence.

40 THE COMMISSIONER: Your client has never said that she tested any patients from any doctors at this hospital other than Professor Hacker.

MS SOARS: I think- - -

MR ALEXIS: And Marsden.

THE COMMISSIONER: And Professor Marsden.

MS SOARS: As, as you please. I agree with that, Mr Commissioner, but I am instructed that perhaps she was having, having put it to her that perhaps she was confused and perhaps she did, did test patients of Dr Campion. They're my instructions, Mr Commissioner.

THE COMMISSIONER: I understand that.

MR SOARS: And I will be leading that evidence in reply.

10 MR ALEXIS: Well, Commissioner- - -

THE COMMISSIONER: If that's to say- - -

MR ALEXIS: In light of what's been put by counsel on instructions, I think it's appropriate that she be permitted to ask questions concerning Dr Campion, but we ought to draw the line after him, with respect, and Dr Robinson and- - -

20 THE COMMISSIONER: Well, that all depends on what your instructions are. I may say this widens the inquiry considerably, comes as a surprise in the light of evidence that your clients has given in previous compulsory examination on two occasions. The investigations of the Commission has been directed to Professor Hacker and none of the other doctors because of what your client has told the Commission.

MS SOARS: Commissioner, that may be the case. I have not seen those transcripts although I have asked for them.

30 THE COMMISSIONER: Mmm.

MS SOARS: And I was not representing Ms Lazarus at the time.

THE COMMISSIONER: That has nothing to do with it. I'm just pointing out to you- - -

MS SOARS: As, as you please.

40 THE COMMISSIONER: So that, I'm just pointing out to you that this has the capacity to widen the inquiry considerably. It may mean that other medical practitioners and other members of the staff have to be called. That would give rise to considerable inconvenience to them and to the patients and I do not mean from that that your client should be precluded from putting this case but I do ask you - - -

MS SOARS: Yes, Commissioner.

THE COMMISSIONER: - - - to be very careful about widening the inquiry in this way because of the cost and inconvenience, often to people who are

seriously ill as a result of what this is apparently doing in the light of the fact that it hasn't been raised before.

MS SOARS: Commissioner, I can't, when I'm in a position to control the questions my client is asked and perhaps they were not quite broad enough or they were asked in a pointed sort of way which didn't give her an opportunity to explain and perhaps for this misunderstanding to come out, they are very serious allegations against my client and these are my instructions.

10

MR ALEXIS: Could I just have a word with my learned friend, Commissioner?

THE COMMISSIONER: Yes.

MS SOARS: Commissioner, if I could ask for a five to ten minute adjournment to take some instructions.

20

THE COMMISSIONER: Yes, I think it would be a good idea. I think it is also important to note, for everybody to be aware and I'm not saying this in any sense other than to make sure that everybody concerned is aware, that lying to the Commission is a serious offence that attracts a penalty of a maximum of five years' imprisonment so care should be taken at all times to ensure that the truth is being told to the Commissioner.

MS SOARS: Yes.

THE COMMISSIONER: We'll adjourn.

30

SHORT ADJOURNMENT

[10.49am]

THE COMMISSIONER: Yes, Ms Soars.

40

MS SOARS: Commissioner, I am instructed that my client in the private examinations did mention that she tested women with abnormal pap smears and that she did mention that she met with another doctor on one occasion who she couldn't name, but I'm instructed now she thinks perhaps it was Dr
Campion. And who came upon her when she was testing a patient and she gave him some literature. And she had already said that in the private examination. And I am instructed that she, she does contend that, that she saw patients who had abnormal pap smears. She obtained patient lists from the general reception desk, which involves more doctors than just Professor Hacker. But on the evidence given it would only involve Dr
Campion and he would be the only one - - -

THE COMMISSIONER: Yes.

MS SOARS: - - - in my submission who would be affected.

THE COMMISSIONER: That's helpful. Thank you.

MS SOARS: Can I proceed?

THE COMMISSIONER: Yes.

10 MS SOARS: I'll just ask my learned friend to remind me what was my last question because I don't have a note of it.

THE COMMISSIONER: You were asking, you were asking Ms Barlow about the doctors who were there and she'd given you a list of the doctors.

MS SOARS: And the dates on which they had conducted clinics and - - -

THE COMMISSIONER: Mmm.

20 MS SOARS: Okay. Thank you, Commissioner. I think I had also asked you did you know how many, maybe I was at this point, do you how many patients within Dr Campion's patient lists may have an abnormal pap smear?---I couldn't answer that accurately.

You don't know. You can't make an estimate?---It would be a guesstimate, perhaps 50 per cent of them.

30 And is it true he specialises in just dealing with people with abnormal pap smears?---But they would be, there would be follow up patients as well that were clear at that time.

For review?---Yeah.

THE COMMISSIONER: Ms Barlow, you were in the, you were in the nurses office when you were working on the Tuesdays and Thursdays?---I spent almost no time in the nurses office.

40 So where were you on the Tuesday and the Thursday?---(not transcribable) centre.

In the clinic were you?---I come in and out of the clinical room, we go across to rooms as well.

Right?---He, he consults within two rooms, Professor Hacker does. As does Dr Campion.

And if, if Ms Lazarus conducted tests on Dr Campion's patients do you know from whom she could have got the name of the appropriate patients

from to carry out the tests on?---The only person she could have got it from is Emma Knowland.

Why, was Emma Knowland - - -?---Emma Knowland worked with Dr Campion as well.

Yes. All right. Thank you.

10 MS SOARS: Could this diagram be marked perhaps, Commission, for identification? I wish to ask some questions about it.

THE COMMISSIONER: Well, I think we'll tender it as an exhibit.

MS SOARS: Tender it.

THE COMMISSIONER: Yes.

MS SOARS: As the court pleases, as you please, Commissioner.

20 THE COMMISSIONER: The diagram, a rough sketch penned by Ms Barlow will be Exhibit 12.

#EXHIBIT 12 - ROUGH SKETCH PREPARED BY MS BARLOW

30 MS SOARS: Ms Barlow, is it true that Professor Hacker's rooms were in the, what you call the main offices on the diagram?---Yes. He's in the main office. His consulting room is down in the, where I've written consulting rooms. There's, it is a very rough draft. I'd need a lot longer to do a good one. Where the two consulting rooms are opposite one another, there's actually two consulting rooms on each side. In the middle of those is a quiet room and on the opposite side a storeroom. So between those two consulting rooms each side.

And within the (not transcribable) offices you've given evidence that's where you worked most of the time. Is that correct?---Monday, Wednesday and Friday generally.

40 And it's where Helen sat?---Yes.

And it's where files relating to Professor Hacker's patients were kept? ---Yes.

And it's where a space was available, was made available for Sandra Lazarus to work. Is that correct?---I'm not sure if within that office a space was made available. I just know that from time to time she'd be at, she might've been at one of those desks.

I'll come back to that. Could I call for Exhibit 4 please, Commissioner?

THE COMMISSIONER: Do you want the original? What is it?

MS SOARS: I don't have a copy of it unfortunately. It's not in the evidentiary bundle. It's the protocol that was supplied by email by my client to Professor Hacker. Did you ever see the protocol that Ms Lazarus provided to Professor Hacker which I have handed to you and which is Exhibit 4?---Not that I recall.

And were you aware that Sandra Lazarus had proposed a study of 200 female patients?---I don't recall that number, no.

And (not transcribable) general study of cervical cancer type symptoms. It says in the protocol that, as attached in this email. Were you aware of that? ---Not the protocol, no.

You've given evidence haven't you Ms Barlow that you referred a number of patients to, well a few patient to Sandra Lazarus and - - -

THE COMMISSIONER: Three.

MS SOARS: Three. Thank you, Commissioner. And in respect of some there may have been some testing. That's correct?---That's correct.

And did you ever see Ms Lazarus' laptop that she was using or the Medex black box?---I don't recall that I did.

And did you ever see Ms Lazarus with files or papers when you saw her in the area?---I'm just not sure. I don't recall that I did.

And did you, did you see Ms Lazarus' files and laptop and the Medex black box stored under a white stool behind, in the filing area behind where Helen sat?---No.

You don't recall seeing it?---I don't recall seeing it.

It's possible it was there from time to time?---I don't recall seeing it.

THE COMMISSIONER: Did you ever have to go to that area to find things?---To the area behind Helen McGilligan's desk?

Yes?---Yes, sometimes I would, I'd pull a file that she had on her shelf or something like that. I would, would stand behind her chair.

How often generally?---Once a week maybe.

MS SOARS: Ms Barlow, assuming just for the purpose of my question that Ms Lazarus may have tested some patients who had abnormal Pap smears who were not patients of Professor Hacker, you wouldn't have been aware necessarily that she was doing that would you during the period 2008?---I had a conversation with Emma Knowland on at least occasions about recruiting for Sandra Lazarus and she had not recruited anyone at that time. This was in later 2008. She made the comment to me that she had rung Sandra on her mobile and was unable to get through.

10 Yes, thank you. You've given evidence of what Emma Knowland told you, your own personal knowledge, you, you may not have been aware that she was testing women with abnormal Pap smears, is that correct, during the period 2008?---I can't understand how I wouldn't be aware but - - -

You accept that you may not have been aware.

THE COMMISSIONER: No, that's not her evidence.

20 MS SOARS: Okay?---I don't really, I don't accept that I wouldn't have been aware.

And how would you have been aware if they weren't patients of Professor Hacker?---Well, I've, I've answered that question but you've said that I've referred it as hearsay really from Emma, Emma Knowland.

So, so - - -?---So that's how I'm aware.

30 That's the only basis for your awareness is your conversations with Emma Knowland?---Yes.

Thank you. Did you ever see an ethics submission in relation to the clinical trials that Ms Lazarus was proposing to carry out?---(NO AUDIBLE REPLY)

THE COMMISSIONER: Sorry, I beg your pardon?---No.

40 MS SOARS: Were you ever asked by Professor Hacker to monitor the position in relation to an ethics submission in relation to that trial? ---Monitor the submission you mean, check through it or - - -

Monitor, I'll break it down for you. Were you ever asked by Professor Hacker to, for example, ask for the ethics submission in relation to that trial? ---No.

And were you ever asked by Professor Hacker to monitor, once a submission had been made whether in fact approval had been given?---No, he told me he'd been told that approval had been given but he didn't ask me to check on it.

And it would be part, would it be part of your normal role to do that, to monitor ethics submission by students working within the, the offices?
---Not by students, no. I, I don't, I monitor any of Professor Hacker's actual projects. I haven't, I haven't been in the practice of monitoring PhD student projects which is something we will alter in the department.

10 And who within those offices do you, do you say would have been responsible for monitoring the, the progress of the ethics submission of Sandra Lazarus as clinical trials?

THE COMMISSIONER: Or would anyone have been?---No one in the department. I, and this is my impression, that she, as a PhD student she would have to have a supervisor at the university that she was enrolled at and that would be the general case.

20 MS SOARS: You gave some evidence this morning and I think you've also mentioned in your statement that you're familiar with the process of making an ethics submission and you indicated that you do it by completing details and, and submitting it online. Is, what is, is there another step then in terms of printing it out and getting it signed and then sending a hard copy?---Yes.

That's correct, and you, you just omitted to say that because you weren't asked about that next step. Is that correct?---Yes.

And who is it signed by normally?---The principal investigator.

30 And in respect of a student under Professor Hacker, you would expect that to be Professor Hacker, would you?---Yes. And, no, not necessarily. It would be the principal, the designated principal investigator, but that would not always be Professor Hacker.

Not always, but there's a possibility, a real possibility it would be Professor Hacker?---Yes, it would. Also their supervisors should sign it.

Is that the university supervisor?---Yes.

40 And is there a provision on the form for that to take place, are you aware?
---I can't think at the moment whether there is. I, I filled out my own as I said earlier when I was at university and my supervisors did, they became principal, associate investigators on the study.

I see?---There is a form, there's a format of being able to add investigators at the beginning so you can just click in and add more in.

Is it possible that there could have been a misunderstanding between Ms Lazarus and Professor Hacker about the scope of or the type of patients that

Ms Lazarus was testing and that she, she had always intended to test some patients with abnormal Pap smears? Do you accept that's a possibility?
---I can't answer that question.

MR LYNCH: I object. I object.

THE COMMISSIONER: Everybody objects to that but Ms Barlow has answered the objection.

10 MS SOARS: Were you aware of the precise details of the protocol for the pilot that Ms Lazarus was conducting?---No, I wasn't.

So you're not aware for example whether it involved not only patients with the more advanced cervical cancer or whether it could also have involved some patients with just abnormal Pap smears for a reference against the earlier patients?---It certainly didn't involve advanced cervical cancer.

20 Yes?---I, I was a little unsure I guess that it involved pre-invasive cancer, I thought it was early stage cervical cancer in my memory of, of looking back on it.

But it would be normal to have a control group within there who perhaps don't have those symptoms against which you can test your results. Is that correct?---It could be. You don't always have a control group, but I don't remember whether that proposal had one or not.

And- - -

30 THE COMMISSIONER: Ms Soars, Professor Hacker's evidence was that there was two categories of people who could- - -

MS SOARS: Yes, Commissioner.

THE COMMISSIONER: - - -be used in the pilot. That seems to be a common ground.

40 MS SOARS: Yes, as you please, Commissioner. You referred to a meeting at which Ms Lazarus gave a presentation in 2007. It's correct, isn't it, that Professor Hacker introduced Sandra as a student of his. Is that correct? Or a student conducting research?---Not a student of his, a student, my memory is of a PhD student, she was conducting a PhD project.

But there is a possibility for example he could have just introduced her as a student, not mentioned anything to do with a PhD, isn't there?---I have memory that it was a PhD. I don't remember that it was just she was a student conducting research, no.

But you don't have a clear memory of which university it was that he said?

---No.

No. So you accept there's a possibility that perhaps he had just said student and not PhD student?

MR LYNCH: I object.

THE COMMISSIONER: That's not what she said. You put it, Ms Soars, but she didn't say it.

10

MS SOARS: I've put the question. Am I entitled to put the question, Commissioner?

THE COMMISSIONER: Yeah, you can put the question that you put it that there is a possibility, you're entitled to put that, but what you're not entitled to do is to say, "You accept that there is a possibility", because that's not what the witness's evidence is so far, but she may change. You're entitled to put the question.

20 MS SOARS: Do you accept that there is a possibility that Professor Hacker introduced Ms Lazarus as a student but didn't mention PhD?---No.

Ms Barlow, when you made your statement you did your best to recall the events to which you were referring in your statement. Is that correct?---I did.

And you did your best, is it correct, to include as much detail in relation to those events as you could remember?---I did.

30 And you didn't in your statement mention the dates on which you say you referred patients to Ms Lazarus, did you?---No.

And you have now given some evidence as to those dates?---I have.

THE COMMISSIONER: Were you asked, I must say from my, my experience, for what it's worth, that what's in the statement depends upon what the witness is asked very often, especially matters of detail.

40 MS SOARS: I'm not suggesting any criticism of Ms Barlow - - -

THE COMMISSIONER: I see (not transcribable).

MS SOARS: - - - Commissioner, I am just seeking to test her memory of the dates and I think I need to do that.

THE COMMISSIONER: Well, I'm sorry. You're, you're perfectly entitled to go on in that way.

MS SOARS: And to understand how - - -

THE COMMISSIONER: I was just trying to, to ensure you - - -

MS SOARS: I'll put a, put a question to, to get to that point.

10 At the time you made the statement did you, did you have a recollection of
on what dates you had referred patients to Ms Lazarus?---I, I don't
remember thinking about it at length. I, I think I found it an overwhelming
experience being interviewed by someone from ICAC, it's very out of what
I would normally be involved with. I answered as I could at the time to
specific questions proposed to me. I was asked by a representative of ICAC
at some point down the track to try and think about dates, specific dates and
I was, it was suggested that I try and think about something significant in
my life at that time and I thought about it and I, I remembered very clearly
about my ethics application and the trauma it caused me and I could actually
relate quite clearly to around those couple of months.

20 But you had no records for example of the dates on which you referred
patients, do you?---No, I don't.

And you don't now recall even the names of the patients referred, is that
correct?---No, I don't.

And you haven't been able to, for example, refresh your memory by
referring to any records within Professor Hacker's office, have you?---No.

30 So I put it to you that there's a real possibility, isn't there, that Ms Lazarus
was seeing patients and conducting some clinical trials on them on dates
prior to August and September 2008, in fact commencing as early as March
2008?---No, I couldn't imagine that would be the case.

Can you say on oath that that is not the case?---Yes.

Your recollection is that clear?---Yes.

Excuse me, Commissioner. Thank you, Ms Barlow.

40 THE COMMISSIONER: Yes, thank you, Ms Soars. Mr Hogan?

MR HOGAN: I have no questions.

THE COMMISSIONER: No questions. Mr Lynch?

MR LYNCH: I have no questions of Ms Barlow.

THE COMMISSIONER: Mr Alexis?

MS SOARS: I apologise, Commissioner, there is one more question about the exhibit - - -

THE COMMISSIONER: Yes.

MS SOARS: - - - I am just looking at and I think it will be helpful.

THE COMMISSIONER: Yes.

10 MS SOARS: Could I refer you to Exhibit 12, the plan. Do you have a copy?---I think so.

THE COMMISSIONER: Of your, your diagram (not transcribable).

MS SOARS: Diagram. Could you just, in which, is it correct that Ms Lazarus saw patients in one of the consulting rooms on the left-hand side of the diagram rather than anywhere within Professor Hacker's office? ---Yes.

20 It's correct?---Yes, it's correct.

And was it any particular room that she would be allocated or - - -?---The, the one I remember was the Lletz room, which I've written Lletz room on, on that to indicate to you the room.

And it would have been open to her, would it, to have used other rooms if they had been free if she was conducting tests?---She wouldn't have gone, she shouldn't have gone into one of those rooms without checking with someone, no. There was one other room which is the first consulting room
30 directly opposite the Lletz room that on the second occasion I, I vaguely remember telling her she could use because it was free that afternoon. That's the only two occasions that I, I know that she was directed to a room.

And general patients' lists for all patients that are being seen by doctors within that whole floor are kept at the reception desk adjacent to the waiting room on your diagram. Is that correct?---Their lists, yes, they, they could be crossed off as they come in. Yeah, they're kept at that reception desk just there opposite the entrance into the consulting clinics.

40 Thank you, Ms Barlow.

THE COMMISSIONER: Ms Barlow, can you just tell me where Professor Hacker's rooms are on your diagram?---Consulting room or office?

Both?---Oh, okay. On the diagram you'll see the nurses office and then consulting room.

Yes?---His is the far end.

What on the right?---On the right and opposite that on the left. He runs two rooms consecutively when he does a clinic.

Sorry opposite that, you mean, I don't know what you mean by opposite that. I can see, you've got next to the nurses office there's consulting rooms and there are three little boxes within the big box?---There are (not transcribable) hallways I've tried to (not transcribable) through doors.

10 And, and so - - -?---The, the very far end - - -

The very far end is Professor Hacker. And is that a separate room?---It's a separate room. It's a consulting room. And then directly opposite that you'll see another little square box, a doorway.

Yes, on, on the, above that, above that on the diagram?---Yes.

Yes. And he also sometimes is there?---Oh no, he'll use two rooms.

20 He'll use two rooms?---He'll have patients in the room.

Right. He'll have both, he'd have - - -?---He goes across.

Okay. Now where, where is it that these, the secretary sits, Helen, can you just indicate where she sits, please?---She sits, you'll go up the corridor and to the next set of offices, passing the lifts, you'll see on the diagram.

Yes?---And then in that, that, that rectangle there's the doorway into the office.

30

Yes?---Helen's desk is the big square I've put just to the right inside the rectangle.

Right. And where are these files, where, where does she keep her files?
---The compactus is actually behind Helen's desk through a doorway.

So behind her desk there is a - - -?---On the wall that I've written lifts - - -
Yes?---There's a, there's you know, a whole room in behind Helen's desk which is the compactus areas where all the files are kept.

40

Right. I see. And, and when, I see. So the way, you've shown the waiting room and the reception desk?---Yes.

Right. And, and when you saw Ms Lazarus from time to time you saw her around Helen's desk?---Around Helen's desk or in there, there's a little area just directly opposite Helen's desk, there's a computer and a vacant sort of spot there that, there's also the photocopier is there, so you can access the photocopier machine and, and the fax machine, that sort of thing.

They're opposite Helen's desk?---Yes, opposite.

On another desk?---Yeah, they're against the wall, the fax and the photocopier machine.

Is that, where does she sit? Does she sit with her back to the corridor?
---Helen McGilligan you mean?

10 Yes?---No, she faces out so anyone that walks in she sees them.

So she sits with her back to the lift?---Yes.

And so anybody going into the file would actually have to pass her?---Has to pass her, yes.

And anybody using the fax and the, and the photocopier machine would be in her line of sight?---Yes.

20 Yes. And, and the nurses office, who sits there?---Emma Knowland at the time. That was basically her office. As I have my own office down in the main offices, I would go in there and do a few things. But I spent almost no time in there. So mainly at the time Emma Knowland.

And these other doctors who shared, did they share, you mentioned five doctors - - -?---Ah hmm.

- - - do they share these consulting rooms?---Yes, they all rotate (not transcribable)

30 On different days?---Yes.

And did you work for Professor, Associate Professor Marsden?---At one time years ago, but not at the moment.

Not now. So what nurse did his work?---Emma Knowland.

And where one sees the, where you've told us where the files are kept - - -?
---Yes.

40 - - - in that, what do you call that area?---The compactus.

The compactus. Are all the doctors' files there?---Yes. At any given time there will be some that are out in their offices that they might be working on and that sort of- - -

Yeah, I understand that. And, and what sort of system is there for, for filing, do you have pigeon holes or boxes with letters on or how do you

know how to find a file?---They're in alphabetical order. They have a, the first three letters of their name is in a big sticker on the front of the file and it's always facing out and so you just have to go and you just go through them until you find the file you want.

And there must be quite a lot of files if they're files for five doctors?
---Yes, and they go back quite a number of years. It's very- - -

10 So it would be, and please correct me if I'm wrong, but the impression that I'm getting is that it would be quite difficult for a person who didn't know what was there to go and find, find patients suffering from a particular malady and you'd really have to know beforehand to look for a file before finding it?---You'd have to just start at A and work your way through. It would take you a long time.

How many files all together, are you able to give an estimate about how many there are there?---No, Helen McGilligan would be better, but there's many many.

20 Yeah. All right. Yes. Thank you very much, Ms Barlow. You are- - -

MR ALEXIS: Commissioner, there's just one matter I wish to take up with Ms Barlow before she is formally excused.

THE COMMISSIONER: Yes.

MR ALEXIS: But before I do, may I indicate having regard to the attention given to the internal geography of this area that we're seeking to arrange some photographic material that might assist in appreciating what Ms
30 Barlow is tried helpfully to illustrate in the sketch.

THE COMMISSIONER: Thank you.

MR ALEXIS: Ms Barlow, in answer to some questions from my learned friend, Ms Soars, you referred to the knowledge that you had concerning ethics approval for the clinical trial concerning the Medex device and you said to the Commissioner something to this effect. You said, "He was told that ethics approval had been given but I didn't see it myself." Do you recall in large measure the evidence that you gave on that subject?---(NO
40 AUDIBLE REPLY)

Just in respect of the reference to he, was that Professor Hacker?---Professor Hacker.

Thank you. And how did you come to understand that he, that is Professor Hacker, had been told of ethics approval?---My memory is that he told me that Sandra Lazarus had ethics approval and I could now identify some patients for her.

Now, on the question of timing, and you've been able to help us with that, approximately when did Professor Hacker convey to you what Ms Lazarus had indicated to him about approval relative to the identifying patients and referring as you've spoken of?---I can't answer that exactly, but it would have been within a couple of weeks that we started finding patients for Ms Lazarus.

Mmm. Yes, thank you, Ms Barlow. Commissioner, I have nothing further and I seek that Ms Barlow be excused from further attendance.

10

MR LYNCH: Commissioner, might I just raise one matter with Ms Barlow?

THE COMMISSIONER: Yes, Mr Lynch.

MR LYNCH: Ms Barlow, can you look at the sketch, Exhibit 12 that you drew. You said that you had an office in what's described as the main offices. Can you identify where in the main offices was your office?---The very far corner, directly opposite the lift, directly down the other end from the lifts on the left-hand side.

20

Thank you. And what's the, the, what's featured between that office and, and Helen McGilligan's desk?---Another big open-plan desk that potentially three people can sit.

And what's the distance, can you estimate, between the office where you located yourself and, and the compactus, say?---Oh, roughly fifty metres.

Sorry?---Fifty metres.

30

Fifty metres?---Roughly. If that.

THE COMMISSIONER: Ms Barlow, I'm afraid I've got another question. Having PhD students or other people doing tests such as the pilot study, is that a, is that a, something that's reasonably common or is it very unusual in, in, in the clinic?---In the clinic it's rather unusual for outside people doing PhD's to come in but there's a couple of staff members within in the department who have done their own PhD projects in the department that

40

So, but there from time to time I take it, people within the department are doing studies of, of a research kind for a multitude of purposes, I presume? ---Yes.

And it could be for getting further degrees or for earning money?---Usually academic pursuit.

Right. So how many times, how many people in a year would say be involved in this?---In a, in a PhD project?

Yes, approximately or say over a period of five years?---Two, three.

And when you've seen it, you've seen it often because you've been, or have you, in the light of your considerable experience this is, you must have seen quite a number going through the process?---I've seen a lot of research projects conducted through the department but not all PhD projects.

10

Yes. When you say a considerable number, what do you, have you got a ballpark figure?---At any given time there could be three projects happening.

To undertake such a project do you need ethics approval every time?
---Every time, except for in the circumstance where no patients will be addressed.

20

So whenever, whenever the research project involves the examination of patients or the participation of patients, you need Ethics Committee approval. Is that right?---To approach a patient you do.

And in your experience has there ever, is it, is it common for research projects to be undertaken without ethics approval in the belief that at some time in the future ethics approval would be given?---Oh, no, never. Absolutely never in my experience.

30

Is that something frowned upon?---Oh, it's completely unethical. Yes, it's absolutely wrong.

Yes, thank you. You are excused, Ms Barlow. Thank you for attending.

WITNESS EXCUSED

[11.37am]

40

MR ALEXIS: Commissioner, if convenient I'd seek to have Ms Lazarus recalled so that I can hopefully conclude her examination with respect to the Royal North Shore Hospital.

THE COMMISSIONER: Yes. Ms Lazarus? Ms Lazarus, please be seated. You're still under your oath and the Section 38 order that was previously made continues to apply to you?

MS LAZARUS: Okay. Before Mr Alexis begins, may I be permitted to speak to him?

THE COMMISSIONER: No?

MS LAZARUS: Can I answer a question?

MS SOARS: Could I just seek a short minute to confer with my client, Mr Commissioner?

10 THE COMMISSIONER: Yes. I think it would be helpful. I think it would probably assist if you explain to Ms Lazarus, as I have previously attempted to do, how these procedures work. What your role is and what everyone else's role and that you are her counsel and you speak for her.

MS SOARS: Thank you.

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

SHORT ADJOURNMENT

[11.39am]

20

THE COMMISSIONER: Mr Alexis.

MR ALEXIS: Thank you, Commissioner.

MR ALEXIS: Ms Lazarus, on Monday afternoon I was examining you in relation to your first and subsequent communications with Professor Ross Smith at that hospital. There was just one further aspect of that that I wish to take up with you before asking you some questions about other aspects. Is it the case that when you spoke with Professor Smith about the proposal to conduct a clinical trial using the Medex device on patients at the hospital, did you indicate to him that the cost, if there be any cost associated with the conduct of such a trial would be covered by funds provided externally of the hospital from a sponsor?---Yes, that's correct.

And so should we understand that on the subject matter of cost and funding from what you said to Professor Smith, you left him in no doubt that if there was to be any cost of you undertaking any such studies - - -?---Ah hmm.

- - - those costs would be entirely covered by monies provided externally from the hospital?---That's correct.

Such that the hospital would not incur any of the cost itself?---That's correct.

And that related to not only the conduct of the trials by yourself but also any associated work, be it marketing or the work of others?---That's correct.

All right. Now do you recall on Monday as well transcript page 106 about line 40. And again, Ms Lazarus, that's a reference for the Commissioner? ---Oh, okay.

We were dealing with the completion of the application for access to the computer network in relation to your sister, Michelle. And do you see, it says here on the screen the question that I sought to ask you, as you'll see there, the clarify that having completed the personal details you also completed the crossing of the boxes on page 147, completed the information on page 148, provided the document to your sister, who then attended Professor Burton and you see your answer, that's correct?---That's correct. Yes.

And just so that we're clear, do you still have the examination bundle? Perhaps you don't?---No.

Could we provide Ms Lazarus, please, thank you, with Exhibit 1. And would you turn it up to page 146. So we're clear with the document that we're referring to, you see the copy application for computer access from page 146 to 149 inclusive?---That's correct. Yes.

And then if you could just look at the screen again you'll see that I sought to have you confirm that the document was provided to your sister?---Ah
hmm.

You told us that as far as you're concerned she then attended on Professor Burton?---That's correct.

Procured his signature?---Yes.

10 And it was then returned to you, I think you said with both signatures on the page and then you submitted it for processing?---That's correct.

All right. Thank you. Now, in the period that we're concerned with here, that is around October 2008 did you yourself have any conversations at all with Professor Gil Burton?---Yes, I did.

And was that in company with your sister Michelle or was it independently of her?---Independently of her.

20 All right. And can you tell me please when it was that you first spoke to Professor Burton?---It would have been a month or, maybe a month or so before Michelle approached him, so before October.

All right. So we should understand that in about late September, 2008 you spoke with Professor Burton?---Ah hmm.

30 What did you speak about?---I took a draft outline of what I was proposing in terms of clinical trial, what the device was, a booklet which contained relevant device information and I took that to him and outlined to him that, is it possible to conduct clinical trials on cervical cancer patients and he had a look at that. He has a copy of the booklet that contains all the Medex information as well as just a rough one-page outline of a sample basically built on previous trials or what was possible, yeah, in terms of trials.

Now during this initial conversation with him did you tell him that you were a PhD student at a university?---I already had a badge that outlined my status and that badge was authorised by Professor Ross Smith.

40 Perhaps you didn't understand my question. When you initially - - -?---No, I didn't mentioned what, if, whether I was a student or not. I was just a researcher that I went, as a researcher I went. He never inquired, there was never a conversation about my status there.

All right. Just so we're clear, your evidence is that you introduced yourself to Professor Burton as a research student?---That's correct. I, I fully - - -

You did not introduce yourself as a PhD student?---No, I fully announced myself as Professor Ross Smith's student.

I see. Now, when was your next communication with Professor Burton?
---Oh, maybe a week or so after I made appointments to see him. There was also a telephone conversation, again following exactly the same procedures in terms of protocol, drafts, pilots, study protocols. They were all developed and given to him.

Sorry, what was developed and given to him?---Protocols.

10 So you prepared a protocol document - - -?---That's correct.

- - - and you handed it to him, did you?---That's correct.

All right. And did you have any further discussions with him in the 2008 year?---Yes, as to where I should be recruiting patients for this particular pilot study according to the protocol that was given to him which he approved. It outlined ten patients and at that point he said I must go see Sue, I mispronounce her last name, Valmet, Valdermere.

20 You've heard of Dr Sue Valdermere, V-A-L-D-E-R-M-E-R-E, is that right?
---That's correct, and an appointment was made to go see her after following the conversation with Gil Burton. So I went and got, went and saw Sue at her office. We had a lengthy conversation. She said that there will be patients available for me to screen for the larger trial. There was no mention of the pilot trial with her.

All right. Now just coming back to Professor Burton, during the conversations you've averted to in 2008 with him, did you come to learn what his area of speciality was?---That's correct.

30 What was it?---Of gynaecology and obstetrician.

And what about Dr Valdermere?---Similarly.

Righto. And just taking a step back to Professor Ross Smith, did you understand that he had an area of speciality?---Yes, that's correct.

And what was that to your knowledge?---Breast and gastrology.

40 Now during the conversation or conversations you had with Professor Burton, did you discuss with him the subject of ethic approval?---Yes, that's correct.

And did he tell you that in relation to any study that might be conducted it was necessary to procure such approval from the Human Research Ethics Committee of the hospital?---Oh, no, he didn't.

Sorry, he didn't?---No.

I see?---The conversation related to me still developing the ethics application.

All right?---I told him of that, because he hadn't, for him to be part of a clinical trial he needs to be able to sign certain documentation and Ethics Committee contacts him directly.

10 Well, can I just be clear then, during the communications you had with Professor Burton and later with Dr Valdermere and before as you would have it, you undertook any clinical tests was there ever a conversation with either of those two doctors about the need to obtain ethical approval before seeing a patient?---That's correct.

All right. When was that conversation?---In the earlier conversations I mentioned to both that I'm in the process of developing the ethics application. They said that's fine, when it's prepared for me to give them a copy. And that was it.

20 And so was it the case that Professor Burton told you that no trial could be undertaken without approval from the Ethics Committee being obtained? ---No, at no point he said that.

So are you telling the Commission that there was discussion with him about you preparing an ethics application - - -?---That's correct.

- - - but he never went the next step and said to you that you couldn't do anything without getting approval?---No. He, all he mentioned was that I am to prepare that ethics application and get that to him for him to look at.
30

Right. And did you have an understanding based on that conversation and the fact that you did subsequently take steps to prepare the ethics application?---That's correct.

And I'll come to the document in a moment, madam?---Okay.

But did you come to understand that it was necessary to submit that application and get it approved before undertaking any trial work?---Oh, no.

40 You didn't have that understanding?---Sorry, can you repeat that question?

Yes. When you spoke with Professor Burton and you subsequently attended to the preparation - - -?---Yes.

- - - of the application for ethical approval - - -?---Ah hmm.

- - - did you understand that you couldn't undertake any testing on any patient using the Medex device until approval had been obtained?---No, that's not correct.

Well tell me why that's not correct?---Because in all trials I've always, they've always given me approval to begin the trial without ethics approval. If for example you go back to - - -

10 Well, I don't want to go back?---Okay.

I'd like to go forward if I may?---Yeah, well - - -

Can you tell me please - - -?--- - - - (not transcribable) like to show why my understanding and where my understanding comes from.

Well let me ask you this question for clarity?---Okay.

Is it the case that after speaking with Professor Burton - - -?---Yes.

20 - - - and before undertaking the first test - - -?---Ah hmm.

- - - of any patient at Royal North Shore Hospital - - -?---Yes.

- - - you were told that you could proceed with the examination of that first patient without obtaining ethics approval?---That's correct.

Thank you. Who told you that?---Gil Burton.

30 Anyone else?---And Vaux, Kenneth Vaux.

You're referring to the doctor whose surname is V-A-U-X?---Yes, that's correct. Yes.

I've been pronouncing it Vaux, but I'm told, I hope reliantly that it's pronounced Vaux?---Vaux.

All right. Is that, is that how you refer to his surname?---I've been saying the same.

40 All right. So are you telling this Commission that both Professor Burton and Dr Vaux - - -?---Yes.

- - - told you that you could commence - - -?---Begin testing the patients.

- - - or being the performance of a clinical trial using patients at the Royal North Shore Hospital - - -?---Yes.

- - - prior to and without obtaining approval from the Ethics Committee of the hospital?---That's correct.

All right. When did Dr Vaux tell you that?---In a conversation we had in the cafeteria after his clinic, when, when I gave him all the protocol and all the information. This was several meetings after. He was there with some of his research staff as well, as well as another, his attendee as well.

10 So this was a meeting in the cafeteria at which - - -?---That's correct.

- - -Dr Vaux and a colleague of his were present. Is that right?---That's correct.

I'll come to the detail of that in a minute. But it's your, that occasion you tell the Commission that he gave you - - -?---That's correct.

- - - verbal approval - - -?---That's correct.

20 - - - to proceed without obtaining approval from the Ethics Committee?---I, he was aware - - -

Is that right or not?---Yes, that's correct.

Thank you. Now Professor Burton you said also - - -

MS SOARS: I object, Commissioner. The witness hadn't finished her answer.

30 MR ALEXIS: All right. Was there something you wished to - - -?---Yes, I do. I should be allowed to complete my answer as well.

Of course you can?---It was, he was aware I was preparing the ethics application at which point when I did meet him the next time and I gave him the protocol he said, you may start.

40 All right. Thank you?---He was very well aware that I was still preparing the ethics application. So what, the words you put forward, not yes to what your question is, but yes, he was aware that the ethics application was not- - -

THE COMMISSIONER: Not only he was aware, he expressly told you that you could- - -?---Could, yes.

- - -proceed to carry out the tests without Ethics Committee approval? ---That's correct.

MR ALEXIS: And, Ms Lazarus, you tell the Commission, do you, that Professor Vaux used these express words, "You may start?"---Yes, "You may begin screening patients", yes.

10 All right. Thank you. Now, just back to Professor Burton for a moment if I may. Are you able to tell me when it was during the conversations with him that he told you that you could proceed to undertake clinical trials without obtaining ethical approval?---He again was aware that I was developing the ethics application and he said, "That's fine, you can go ahead with the ten patients."

And when was that?---Um, in several conversations before I began. I can't tell you the month, sorry. I'm just unclear on that.

Thank you. Was there a particular reason why having initiated communication with Professor Burton about a month or so before the computer access form at page 146 had been completed- - -?---Ah hmm.

20 - - -that that form was taken by your sister, Michelle, to Professor Burton to obtain his signature?---Um yes. Um- - -

30 What was that reason?---We um, we were contacted by Johel um, in terms of the cervical cancer vaccine that um, before we start this clinical trial that because the vaccine was getting a lot of publicity um, this Medex test should um, basically, like, explore the publicity that vaccine is getting as well. Um, so he contacted us and said, "Well, speak to the supervisor of the trial, see how you can maximise Medex um, publicity in association with the vaccine for the cervical cancer." Um, at that point um, I suggested to Michelle, "Michelle, that's the supervisor, if you'd like to speak to him you can go ahead and speak to him." Um, ah, and I believe Michelle made an appointment and um, and she was instructed to get um, by Gil Burton and she was instructed to get, I don't know the details of the conversation, but um, instructed to him by um, so Michelle was instructed that she needs to go obtain some sort of formal registration. She called me up because we were there at the same time, not in his office, but I was in the Kolling Building. She called me and she said, "Oh, he's asked me to get some sort of access." I said, "Oh, O.K. I know what it is." Um, I went down to level 7 where there is the um, university and where I'd accessed, where I'd got my form from and where I met the practice manager to get other registration ID card, 40 and um, that's where I got the form, filled it out, she met, I met, I gave it to her downstairs and she went upstairs and their conversation continued.

So your evidence is that your sister, Michelle, told you that the need for the form at 146 and following of the examination bundle- - -?---Ah hmm.

- - -was the result of an instruction from Professor Burton. Is that right?
---That's correct.

And it was in the result of that that it was completed and taken to his as we've discussed?---That's correct.

Was it ever intended, as far as you're concerned, for your sister, Michelle, to undertake any of the clinical testing herself?---No, no, no. She's not um, Michelle cannot do any of the clinical tests, she's not um, trained, only Jessica has full training qualifications.

10 Right. Now, could I just ask you a couple of questions concerning Dr Vaux?---Yes.

Should we understand that you initially contacted him by telephone- - -?
---That's correct.

- - -in the late 2008 period?---Um, yes, that's correct.

And what did you understand that- - -?---Mid to late.

20 Thank you. What did you understand Dr Vaux's area of specialty to be?
---Um, ah, urology.

And is it the case that you then had the cafeteria meeting that you've just spoken about?---The very first meeting was in the cafeteria meeting, yes.

Yeah?---Not the one that I spoke about earlier.

30 Sorry, there was another cafeteria meeting, was there?---There were several. He always finished his clinic, I've always met him in front of, in the cafeteria in front of the Gloria Jean's.

So is it the case then that having spoken to him on the telephone- - -?
---Ah hmm.

- - -you then met him on more than one occasion- - -?---Oh, several occasions. I even showed him the graphs in the cafeteria.

40 And by several, what should we understand that number to be?---Um, exceeding, exceeding 10, 12, 'cause there was occasion, the initial meeting then again another meeting with the protocol, um, that's when his attendee was there as well.

Ah hmm?---Then there was another meeting um, when I explained to him what I'm doing, how many patients I'd completed at that stage. I went through the graphs with him as well. Um, then there was another talk of, then there was another meeting where he wanted me to do a small presentation and to call one of his other attendees or research assistant he was, I'm not quite sure who he was. But- - -

Can I just go back to the first cafeteria meeting?---Yes.

And can I just show you this document, please. Now, Ms Lazarus, could you turn please to the fourth page of that document?---Yes.

And do you see just for identification purposes that the top of that page is headed, Head of Departments or Delegated Officers' Recommendations and Report? Do you see that?---Yes, that's correct.

10 And do you see about halfway down adjacent to the typed word, supervisor - - -?---Yes, that's correct.

- - - we have Dr Vaux's signature together with his date of birth and his department location?---That's correct.

And is it the case that during the first cafeteria meeting you had with him you asked him to sign that form in the position identified on the document that's before you?---There is no way he would sign, agree to be my supervisor in the first initial meeting.

20

So should we understand from that answer, Ms Lazarus, that you asked him to sign this form, perhaps not at the first cafeteria meeting but at a subsequent meeting?---Oh, definitely.

All right?---Um, he, at this stage he's, he'd already seen um, at least a few patient graphs which would be after showing him protocols, showing him other details about Medex, discussions about ethics applications. There's, there's no way he would sign, agree to be my supervisor in the first meeting.

30 Tell me, when you first spoke with Dr Vaux, did you convey to him that you were a PhD student?---No, but that's why I needed this form and he needed to sign it so I can be re-enrolled.

I see. And so did you tell him that you were seeking to be re-enrolled as a PhD student?---That's correct.

Did you tell him that Professor Ross Smith was proposed as your supervisor?---That's correct, as the coordinator, yes.

40 Coordinator. Thank you. And it was after telling him about what Professor Ross Smith's role was to be in relation to your studies that you asked him to sign this form and he did, as we see in the document I've provided to you? ---Yes, after several meetings, yes.

You say several meetings before he signed?---Yes.

What should we understand you to mean by several?---Like, like I mentioned earlier, it would have been at a stage where at least a handful, a number exceeding ten patients would have been screened already.

Thank you. Commissioner, I propose showing this document in due course to Dr Vaux, so I would ordinarily have it marked rather than tendered, but in light of the evidence it can perhaps be tendered and we can come back to it in due course.

- 10 THE COMMISSIONER: The application for admission into University of Sydney research course in 2009 signed by Dr Vaux is Exhibit 13.

#EXHIBIT 13 - APPLICATION FOR ADMISSION INTO UNIVERSITY OF SYDNEY RESEARCH COURSE IN 2009 SIGNED BY DR VAUX

- 20 MR ALEXIS: Ms Lazarus, could you turn up page 151 and following of the examination bundle, please?---Sorry, 150?

151?---I don't have that.

Do you have 151?

Could I have access to the bundle that is before the witness, please. Thanks. Ms Lazarus, the examination bundle should now be open at page 151?
---Yes.

- 30 And do we see there a document addressed to the Royal North Shore Hospital Human Research Ethics Committee with, after the text, provision for each of the various professors and doctors to sign?---Yes, that's correct.

And that's a document you prepared?---That's correct, that's a draft copy.

And may we take it that you prepared this document after having the conversations that you tell us of with Professor Ross Smith, Professor Burton, Dr Valdermere and Dr Vaux as we've discussed?---That's correct. I wouldn't have known who to put down (not transcribable).

- 40 And was the purpose of preparing this document to facilitate the lodgement of the National Ethics Application Form and the accompanying Site Specific Assessment Form?---That's correct.

And do we see a draft of that document that you prepared commencing at page 153 of the bundle and continuing through to page 204?---Yes, that's correct.

Thank you. Could you turn to page 158 please. And do you see about halfway down the page in answer to the question concerning the start and finish dates for the whole of the study referred to in the document you've entered the date 14 November, 2008, do you see that?---That's correct. That's roughly the time when this application was developed (not transcribable) draft.

10 Well, I'm just going to confirm that with you. May we take it that you prepared the draft applications and the draft document at page 151 ready for signature by the doctors prior to 14 November, 2008?---That's correct.

Approximately how long before that date did you prepare these documents?---It would take several, several weeks for me to put through, well, put together an application like this. It involves a lot of work. The protocol needs to be, it would take several months to be able to put through a proper protocol, especially when it contains three studies, then another new, brand new study for cell D research for breast cancer, looking at doing a lot of cell work so it would take a very long time.

20 THE COMMISSIONER: The question is when did you start? When did you start preparing this document?---After my, after my, a few conversations with Professor Ross Smith in terms of putting together, begin putting together an ethics application.

MR ALEXIS: And if we look at page 159 we see under the heading "General Background" that the proposed trials - - -?---Yes.

30 - - - were to relate to the early detection of cervical cancer, you see paragraph 1.3.1?---Yes, that's correct.

Breast cancer, you see in the next paragraph .2?---That's correct, yes.

And over the page prostate cancer at paragraph 1.3.3?---That's correct.

And just to relate the particular doctors that we've discussed, the first subject matter cervical cancer was with respect to Professor Burton and Dr Valdermere, is that right?---That's correct.

40 Breast cancer was with respect to Professor Smith?---Yes, that's correct, that's what - - -

And prostate cancer with Dr Vaux?---That's correct. The, the breast cancer one is, includes the (not transcribable) cell D research as well.

Yes, which is the area that Professor Smith suggested you might consider researching as part of your PhD studies?---That's correct.

Thank you. Can I ask you to come through to page 186 of the draft Application for Ethical Approval and do you see in similar - - -?---Hang on.

- - - format to the earlier application we examined on Monday in relation to the Royal Hospital for Women there is the table which required a response in relation to funding, do you see that?---That's correct, yes.

10 And should we understand that you were then at the time of preparation seeking external competitive funding?---No, to the best of my knowledge funding had already been provided by Sydvat.

All right. Well, just so I understand, madam, you see on page 186 under the heading "Funding" in the box there's the words "External competitive grant." Do you see that?---Yes, yes.

And you've bulleted the word "sought" in the next column?---Yes, I've done the same for the Royal Women's as well as you mentioned so it's just a copy of how to keep answering the same questions exactly the same way.

20 All right. And you then had in mind, did you, that the project in whatever form might be approved would be funded 100 per cent by external sources? ---That's correct.

But is it true to say that at the time you prepared this application prior to 13 November, 2008 the source of that funding was not as yet known?---No, it was always Sydvat.

Well, could you look at the document at 186 - - -?---Yeah, no, I - - -

30 - - - about halfway down the page, you know what I'm referring you to, don't you? You've put there "Not known as yet?"---Yes, that's correct.

Well, why if Sydvat was to be the sponsor for trials at the Royal North Shore did you not identify that body or organisation as the funder?---I've done the same error in the other one as well. Like I said, it's just, I followed it through in terms of answering the question exactly the same way where I would have a hard copy and I've just, it's my error.

40 THE COMMISSIONER: I understand it's your error but I don't understand why you did it because if you obviously, if you hadn't, if you knew who it was I don't understand how you can make the error?---Well, I should have written it, yes.

Unless you were deliberately not saying who it was?---No, no, it was always Sydvat.

So the Commission can understand that it would have been a simple thing for you to insert the details of Sydvat or a Medex company or Dr Neiron's - - -?---Or the, that's correct.

- - - business entities - - -?---Yes.

- - - because at the time you prepared this document you understood, did you, that Dr Neiron was going to be the funder?---But he already had deposited funds.

10

And tell me, how, how was it that you knew at the time, and let's be clear, we're talking about the period up to 14 November, 2008, how was it by that time did you understand that Dr Neiron and his companies were going to sponsor clinical trials at Royal North Shore Hospital?---When I spoke to him in a conversation he said that the funds were provided, it was all set up at the Royal North Shore Hospital, that I can continue. That was because I provided him with the protocols again exactly in the same manner as I did in the earlier clinical trial. The protocols were provided to him and then he starts putting in the funds, that's exactly what he told me.

20

All right?---He said the funds will be in after two weeks and I had no reason to believe why they wouldn't be.

Can I seek to get some clarity around that?---Yeah.

When do you say you spoke to Dr Neiron about the subject of his company or companies funding - - -?---Yes.

30

- - - trials at the Royal North Shore Hospital?---It would be early to mid 2008.

So in the 2008 year?---Yes.

And this is during the course of discussions with him, was it, concerning the depositing of funds in the Royal Women's Hospital or the GO Research Fund - - -?---Yes.

- - - that you've told us about?---Yes.

40

How much did he say either was or would be deposited with the Royal North Shore Hospital for trials on patients?---Roughly about 600,000 he said.

600,000?---That's correct.

I see. And did he tell you during those conversations when payments totalling \$600,000 were going to be made?---Yes, he said in the, as soon as I give him the protocol and then start giving him, exactly in the same manner,

protocol, draft of the ethics, signed ethics agreement and follow on with all the test results and things like that. I was showing him test results when I completed on a regular basis so I had no reason to believe that he was ever upset with the work I'd completed or hadn't deposited anything. The fact that the facts were available were also voiced to Professor Ross Smith as well.

10 I may have misheard you, Ms Lazarus, and forgive me if I have. But did you say that he said to you that he would provide funds up to \$600,000 after you gave him the protocol document?---That's correct.

And that's the document you gave to Professor Burton?---Yes. No, that's the initial protocol that I began preparing which contained all this information. The protocol I gave Professor Burton was only a section of that.

20 I see. And did you also mention in your answer before last that you also provided Dr Neiron with ethics approvals?---Ethics applications, not approvals.

I see. So the promise of funding by Dr Neiron's company followed you providing to him the protocol that you've described and also a copy of the ethics application?---Yes. Yes, but in a systematic manner, not all together.

And did his promise - - -?---It was at the milestones that he always set out.

30 All right. And did his promise of funding indicate to you that funds would not be paid unless and until an approval of your ethics application had been obtained?---No, never. I'll have to use an example previously, in St Vincent he was well aware that we were still in the process of obtaining ethics application, but the full promised amount that he said for \$47,000 was already deposited into St Vincent. So based on those reasons I had no reason to believe that if we are still in the ethics application development stage that he will not be putting funds in.

But at any stage did he say to you that he wouldn't part with any money unless and until approval of the ethics application had been obtained?---No, none whatsoever.

40 THE COMMISSIONER: You said earlier that Professor Ross Smith said something about this and I couldn't quite understand what you were saying?---Oh, no, I was just saying that I was, I voiced that to Professor Ross Smith as well. I let him know as well that the funds are, I've been told the funds have been deposited.

Do we know exactly what this protocol is?

MR ALEXIS: No. It's represented in a document form and as an attachment to an email to Professor Hacker, which is comprised, comprised within Exhibit 4. As we understand, Commissioner, that's the only documentary representation of the protocol that we have. Ms Lazarus, can I just step back only ever so briefly to the Royal Hospital for Women. You've been provided I think with Exhibit 4, which is an email that you transmitted to Professor Hacker - - -?---That's correct.

10 - - - attaching what's described as the experimental protocol. And you've asked him in the email if he could have a quick look. Do you see that?
---That's correct. Yes.

And if you just look at the document which is the attachment to that email which is entitled Clinical Study Protocol?---Yes.

And you look at what's described there as the objectives and the number of participants and other pertinent information?---Yes.

20 Is this document illustrative of what you're speaking of when you refer to a protocol - - -?---That's correct.

- - - in relation to the Royal North Shore Hospital?---That's correct.

So with the exception perhaps just coming back to the first page of the attachment, the reference to Department of Gynaecological Oncology and the number of patients and that - - -?---Yes.

30 - - - none of those details would have been amended to suit the particular areas of specialty, but it's the form of document which we should understand was either very similar or the same as that which was provided to Professor Ross Smith. Is that right?---Yes, that's correct.

Professor Burton?---Yes. And Professor - - -

THE COMMISSIONER: Vaux?--- - - - Vaux.

MR ALEXIS: Yes, I was just going to mention him, Dr, Dr Vaux?---Yes.

40 And what about Dr Valdemere, did she get one as well?---Yes, she did.

Thank you. And so when you were speaking a moment ago about the conversation with Dr Neiron and the subject of procuring funding and you refer to him pledging \$600,000 and you talked about the documents that you provided to him, we should understand that a protocol document as illustrated by Exhibit 4 was the document that was provided to him - - -?
---That's correct.

- - - together with the draft ethics application?---Not, not together. Only the protocol was provided and then when the draft was developed, like I said, it takes a very long time to develop something like that, a while. The draft was provided to him and then he made another set of payments.

All right?---That's, that's what I was told.

THE COMMISSIONER: So the first set of payments came after the protocol?---That's correct. That's what he - - -

10

And how, how much was that?---I'm not quite sure. He divided those up accordingly to the milestones he's always set.

And then, and then the next payment was made when?---When I gave him the draft ethics application. At this stage it would have been, I'm just thinking, 'cause he's always put about four or five milestones to complete before payment.

20

So you mentioned after the, the first time was after the protocol?---That's correct.

The second payment after the (not transcribable) and got the application for ethics approval?---Yes, the draft ethics application.

Yes. And then was there another payment that he made?---Yes.

When was that?---In terms of the agreement, when the agreement was signed and given to him.

30

The agreement between whom and whom?---The Royal North Shore and Johel Neiron. Very similar to the agreement that was between Neville Hacker and Johel Neiron that you have in email.

That's an agreement signed on behalf of Royal North Shore?---That's correct.

And by, and by anyone else?---And by Johel Neiron.

40

And who signed it on behalf of Royal North Shore?---Ross Smith.

And then that's the third payment?---That's the third payment.

And is there another payment?---That's correct. Once I complete 50 patients.

And when did you do that?---When I was told I can begin, so roughly around mid 2008.

By mid 2008 you'd completed 50 patients?---That's correct.

10 And so when did you, so when did you get paid for completing the, when was the payment made because you had completed 50 patients?---Two weeks after he came to the Royal North Shore hospital and I showed him the files of the patients, 'cause he always wants to look at the files of the patients to see and to make sure, basically to check that the work is done. He did that at the Royal Women's Hospital as well. This protocol for example, has been sent, I think 2007, November. I would have sent this to him around the same time. So two weeks after that he would have made the first payment.

Mr Alexis, no doubt you will ask Ms Lazarus about the time that Dr Neiron came to both hospitals and looked at the patient's files.

20 MR ALEXIS: Yes, yes. Ms Lazarus, in relation to each of those payments, how much was each approximately? Do you know?---Like I said I wouldn't know. He would have divided that up with the four or five milestones, he always put in place.

THE COMMISSIONER: Well that sounds like around \$120,000 each? ---That's correct.

MR ALEXIS: But is, is your response to the Commissioner's question that that is correct simply (not transcribable) arithmetic?---Yes.

It's not based on any knowledge?---No, no. Just based on simple mathematics.

30 It's not based on anything Dr Neiron told you?---No, no.

So is this the position, that at the time you started submitting invoices to Royal North Shore Hospital - - -?---Yes.

- - - you didn't know what Dr Neiron had deposited with the hospital?---No. Just, I just knew that those were the five and simple maths that I did allowed me to believe that that's how much money was deposited.

40 So you expected that by reason of compliance with certain milestones - - -? ---Yes.

- - - approximately one fifth or thereabouts of the \$600,000 that was pledged was deposited with the hospital?---That's correct.

But Neiron never told you that he had deposited it with the hospital. Is that right?---No, he did, he said that it's all done. He always said it's all done.

When did he tell you that?---In a conversation, 'cause I always followed up, he always gave me, here, here, complete that milestone, two weeks later the money will be in. I always followed up and said, he's, he's always reassured me it's done. Like I said I never actually took the initiative to check ever.

Now can I just clarify something that fell from you a moment ago when the Commissioner was asking you questions about the existence of an agreement?---Yes.

10

And again I need to go back ever so briefly to the Royal Hospital for Women - - -?---Yes.

- - - and show you the form of agreement that we examined with respect to that hospital commencing at page 96. If you could turn that up, please.

And madam, it was your evidence to the Commission that - - -?---Sorry - - -

Do you have that document?---Yes.

20

Thank you. Is your evidence to the Commission that an agreement for clinical trials in the form that we see at page 96 to 99 inclusive- - -?---Yes.

- - -with the exception of course of Royal Hospital for Women being substituted with reference to the Royal North Shore Hospital- - -?---Yes.

- - -was a document that you presented to Professor Smith for signature?
---That's correct.

30

And can you tell me please when the document in that form as you've described was given to Professor Smith for signature?---Very early in the stage.

All right. Well, I'm going to come in a moment to the documents that Professor Smith is said to have signed?---Ah hmm.

Computer access, email access, vendor maintenance forms?---Yes.

40

Are you telling the Commission that it was in the context of signing all of those documents, which all seem to be a date about October 2008- - -?---Yes.

- - -that the agreement for clinical trials was also signed by him in your presence?---Yes.

All right. Ms Lazarus, we haven't seen any agreement for clinical trials naming the Royal North Shore Hospital as a party, whether signed by Professor Smith or otherwise?---Ah hmm

Do you have knowledge of where that agreement or a copy of that agreement might be?---Yes. The original was always given to Johel Neiron.

So your evidence is that the original agreement was provided to Dr Neiron?
---That's correct.

And when was the original document provided to him?---Um just about right after um, the signature was obtained from Ross Smith.

10

And you didn't keep a copy I gather?---No. Um, you've got the, I've only got the photocopy given for St Vincent.

Now, was any similar type of agreement entered into with respect to Wish Consulting and the conduct of any marketing services for the Royal North Shore Hospital?---Not in base of contract like that.

20

Well, was any form of document entered into in relation to that subject matter?---Yes, that's correct. Um, when the vendor form was presented um, it was presented with the same proposal that was um, developed by Johel Neiron um, and was signed by both Michelle and Johel and that's the same document that was presented to Neville Hacker at the time of when he um, completed the vendor maintenance form as well.

All right. So you're telling the Commission that the form of agreement that existed between Dr Neiron's company on the one hand and Wish Consulting on the other- -?---Yes.

30

- - -dealing with the provision of marketing services- - -?---Ah hmm.

- - -was an agreement that was entered into separately with respect to work to be done at North Shore?---Yes, that's correct

And that was a contract in a written form?---That's right.

Signed by each of the parties?---Yes, that's correct.

40

Dr Neiron on the one hand and your sister, Michelle on the other?---That's correct, yes.

And that was provided presumably with the vendor maintenance form that you asked Professor Smith to sign in late October?---Yes, always, yes.

All right. I'll come to that in a moment. Can I just return to the question of ethics approval?---Yes.

We've discussed the form at page 151?---(not transcribable)

And the application from 152 and following. Did you ever get, pardon me, did you ever get the form of letter at 151 signed by Professor Smith or Professor Burton or any of the other doctors referred to on that page?---No. I was still waiting for their feedback.

Sorry, feedback on what?---On if I need to make any changes in, with the ethics application.

10 So should we understand from that answer, madam, that the draft document at 151 and the draft application that follows it was provided to Professor Smith, Professor Burton, Doctor Vaux and Doctor Valdermere by you?
---That's correct.

And you asked them to look at it?---That's correct.

And you asked them to give you some feedback?---Changes, yes.

And you're still waiting?---Yes.

20 All right. Does it follow from all of that that the document at 151 and the underlying applications were never lodged or submitted by you to the Human Research Ethics Committee?---That's correct.

And it follows I take it that no approval was ever obtained- -?---No, I haven't even locked this form, like, before I mentioned it hasn't even been locked or submitted.

30 You may not have. But the position is that to your knowledge no approval was ever obtained in relation to any clinical trial at Royal North Shore Hospital with respect to cervical breast or prostate cancer?---That's correct.

Now, with respect to Professor Smith, did you ever obtain access to his patient files?---No, there was no need to.

Did you ever obtain access to any of his patients for the purpose of using the Medex device on any of them?---No, there was no need to.

40 And, and the questions that I've just asked you about access to patient files or access to his patients- -?---Ah hmm.

- - -let me be plain with you, was either at his private consulting rooms in the North Shore Private Hospital or in his room in the Kolling Institute of Medical Research?---Oh, his patient files are always kept at his consulting rooms at the um Private Royal North Shore. But there was no need for me to access those, nor did I ever access those because there, the breast trial that was to be conducted at the Royal North Shore wasn't for Medex, for the breast um, that was plainly for the Proteonomix cell research. It wasn't from Medex.

So the position just so we're clear- -?---Yes.

- - -you do not suggest that you conducted any clinical trials using the Medex device- -?---Yes.

- - -on any of Professor Ross Smith's patients?---That's correct.

10 And should we understand that when we examine, as we will in a moment, the various invoices that were- -?---Ah hmm.

- - -generated by you and submitted for payment to the Royal North Shore Hospital and also I include in that those generated on behalf of Wish Consulting, not one of those invoices related to any test or marketing for tests of the Medex device in relation to any breast cancer patients of Professor Ross Smith?---That's correct.

20 Now, in relation to Professor Burton and Dr Valdermere, you didn't examine any of their patients with the Medex device, did you?---No. It was examination with the Medex device for the um, not Sue, not Sue, sorry, how do you pronounce her last name, Valdermere?

Dr Valdermere?---Valdermere, yeah. There weren't any patients from her, they were Gil Burton's patients.

30 Right. So we should understand that in relation to the examination of patients with respect to the testing of the device for cervical cancer, every patient that you examined was that of Professor Burton's?---Of Gil Burton's, yes.

40 Ah hmm. Now, you didn't provide Professor Burton or Dr Valdermere with any result from any testing of the Medex device on any of the cervical cancer patients, did you?---That's not true. Um, Gil Burton was provided with the complete pilot study that was completed. Um, based on that, a report was formulated and based on that report, the Medex CEO, administration at that time, David Pleiksna and Vern Pleiksna, arranged a meeting. So they flew down from Perth to meet Gil Burton. There was a meeting at Gil Burton's office where I was present, David Vern was present um, ah, sorry, David Pleiksna was present, Vern Pleiksna was present and they had a lengthy conversation with Gil Burton in regards to further sponsorship, the fact that they've taken over the company, they're happy with this trial, these trial results. The report that he, he, Gil Burton had signed and approved. They had an original copy, I had an original copy which the ICAC has. Um, that was from my folder. Um, they had a very lengthy conversation. Um, further studies were discussed, further funding was discussed, everything was covered in that, that meeting.

All right. And Pleiksna is spelt P-L-E-I-K-S-N-A?---(not transcribable)

You understood the two gentlemen, Mr Vern and Mr David Pleiksna being executives from the company Medex Test Corporation Pty Limited.---That's correct.

Now that was a meeting that occurred in Professor Burton's rooms in October 2009 wasn't it?---Yes, roughly, yes.

10 Thank you. I'll come back to that if I may but - - -?---I think (not transcribable)

Just in relation to Professor Burton – could you turn over the examination bundle please to page 277.---Page 277.

Now, do you have page 277?---Yes, that's correct.

And do you see that to be a letter which appears to have been signed by - - - ?---Sorry, 277.

20 277.---Sorry, I had 207. Yes, that's correct.

Now this appears to be a letter signed by a Dr Burton addressed to the Medex Test Corporation in Western Australia. Do you see that?---That's correct.

Now the preparation of the letter, were you involved in that?---Yes, that's correct.

30 And tell me what you did in relation to the preparation of this letter?---The letter was prepared, a draft was printed from Gil Burton's office, his secretary printed a draft out - - -

Well, who prepared the draft?---I did.

So you - - -?---I put the results in and the draft prepared.

So we should understand that you draft the letter yourself.---Yes, that's correct.

40 You had it typed up into a computer?---That's correct.

And tell me what happened then?---And then um, I took the, took that, this letter on a USB to Gil Burton's office. I handed that to the secretary, the secretary printed that out on a rough draft - - -

What on a blank piece of paper?---Blank piece of paper, no heading.

Not letterhead?---No.

All right.---And that was taken to Gil Burton for amendments. He made a few small changes here and there.

Well let me just get clear, when it was taken to Dr Burton for his consideration, were you present?---Yes.

10 And what did you see him do when you provided him with the draft?---Oh he read through it and made minor changes with the pen.

And how did, so he corrected the letter with a pen?---Yes.

And what did he do with that draft having annotated corrections?---He gave that to me.

And what did you do with it?---I took that back um - - -

20 And what did you do with it then?---Oh the secretary allowed me to make the small changes, actually she made – I’m actually not quite sure if I made the – I was typing or she was typing and it was followed, the changes were made, it was in the present of the secretary, she was there and then she printed the final copy out on the letterhead and I – two copies – I took that back, both copies to him. He skimmed over the copies and signed both copies. One copy, original I sent through to the Medex Corporation and the other copy I kept with myself.

All right.

30 THE COMMISSIONER: What’s the secretary’s name?---I’m not quite sure.

MR ALEXIS: Now you’re sure that it was the secretary that obtained the letterhead and printed the form of letter out on the letterhead that we see at page 277?---Yes, it was done at his office.

You didn’t obtain the letterhead yourself?---No.

40 And just looking at the text of the letter, you see in the second paragraph on the second line there’s reference to the research team – you see that?---The second paragraph, second line.

You see the paragraph commencing, “as the Medex test is a swirly method,” you drop down two lines you’ll see a sentence commencing, “the research team saw fit to conduct approve (not transcribable) research trial before conducting a larger clinical trial to evaluate the merit of the Medex Test,” Do you see that?---That’s correct.

Who is the research team that you're referring to given that you drafted the letter?---Gil Burton and I and Sue as well but she wasn't involved in the 10 patients of the pilot.

And further in that paragraph there's reference to 10 positively diagnosed patients.---That's correct.

And the letter then seeks to report on the results of that.---That's correct, that's the pilot.

10

And you say that you saw Professor Burton read the amended letter.--- That's correct.

On letterhead?---On letterhead.

And what did you see him then do?---Sign both copies.

And what did he then do both with the original and the copy?---Gave both originals to me.

20

And what did you then do with the originals?---I kept one original with myself and I posted the other original to Medex.

In Western Australia?--- Yes, that's correct.

Now, pardon me. When you prepared the letter and then as you say you saw Dr Burton sign the letter, there'd be no change had there in relation to Ethics Approval?---No, no.

30 You hadn't lodged the application.---No, no.

No approval had been obtained?---No, because um, the Ethics Committee will contact him directly without my knowledge.

All right. Now you mentioned it a little while ago about the meeting and I think you agreed that it was in about October, 2009?---October.

When the executives from Medex Test Corporation attended?

40 MS SOARS: I object, sorry, I think my client said something in the middle of that sentence so she could clarify.

MR ALEXIS: Do you wish to say something about the timing of that meeting?---Yes, but there would be flight records anyway of them flying down.

Yes.---Yes. Like (not transcribable)

Anyway, I'm just asking about your recollection and independently of records, you accept do you that October, 2009 approximately was the time of that meeting?---Approximately, yes.

All right. And after that meeting, is it correct to understand that you had no further discussions or involvement with Professor Burton?---That's correct.

Now turning to Dr Vaux, after the occasion when you asked him to sign the form that we referred to a short while ago, did you ever see him again?

10 ---Yes.

And how many times after you got him to sign that form did you see him?
---Um, I wouldn't remember an exact number but it was always after his clinic at that stage in between – I had completed a significant amount of patients and I did show him the graphs every time.

So in relation to Dr Vaux, you would attend his clinic and you would examine his patients and you would provide him with the graph that we've seen, I think in Exhibit 9 – which indicates the results from the examination of the patients?---I'm going to have to rephrase that because it's been pointed out to me previously, I accessed the patients in the clinic because last time you said to me, oh you've only accessed Hacker's patient or Marsden' patients, I accessed the patient in the clinic.

20

All right. Well we're doing with Dr Vaux and he's at North Shore isn't he?
---Yes but (not transcribable) - - -

But what you're telling me - - -?---There are other doctors in that clinic as well, their patients sit in that clinic as well.

30

But your evidence is that there were substantial tests done - - -?---Yes.

- - -in relation to Dr Vaux's patients.---That's correct.

In the result of which you provided him with presumably a substantial number of colour graphs which were the results of your Medex Test trials?

---Yes, because um, whenever I'd provide them with these colour graphs they always have um, another sample colour graph that outlines what a positive patient would look like. Again, a sample of that is in the white folder which is, which cannot be located, that we have not been able to find at the Royal Women's Hospital but there is a sample of that for the Strathfield Private even though we're not dealing with that. The same, a white folder it contains exactly the same information. In front of it there are sample graphs that I've developed using the algorithms in diagnosing prostate cancer as outlined in the Medex booklet. When I go and see these professors to see how, what the positive should look like, that sample's put in front of them. Based on that, they look at the graph of the patient and determine whether they want to say yes or no.

40

Now what number, approximately, should we understand your evidence about a substantial number of patients with Dr Vaux?---I completed a total of 200 patients with him.

I see.

THE COMMISSIONER: How many?---200.

10 Of Dr Vaux?---Of that clinic.

MR ALEXIS: And when you say of that clinic, we're referring to the clinic in relation to actual or symptomatic prostate cancer patients?---That's correct.

THE COMMISSIONER: At Royal North Shore.---At Royal North Shore.

So that must be about 200 patients from Dr Vaux and Dr Burton?---No, no, no, not Dr Burton, Dr Burton's cervical cancer.

20

So the 200 patients - - -?---Yes.

- - - all came from Dr Vaux?---They all came from that, the, the clinic so there'll be a significant amount that's Dr Vaux's because last time it was pointed out to me that I, it has to be the clinic not the, like last time you said oh, but you said in your testimony that, it's only Hacker's and only Marsden's that you saw and that's it and there can't be anyone else's, but that's what I'm trying to explain. It's the clinic where I got the patient from.

30 MR ALEXIS: All right, well, we'll come back to that in due course. But can I ask you to go to page 288 of the examination bundle. And do you see there, madam, a letter dated 12 June, 2009 address to Inter Medical in Western Australia which is a letter that seems to have been signed by Dr Vaux?---Yes, that's correct.

Now, can I just ask you some questions about your involvement in the preparation of this letter. May we take it that you were involved?---Yes, that's correct.

40 And did you draft the letter?---Yes, that's correct.

And did you, having drafted the letter, do something with it which ultimately led to Professor, I withdraw that I'm sorry, Dr Vaux looking at it? ---Yes, that's correct.

What did you do?---Exactly the same way. I printed it out on a blank white piece without the letterhead. This was shown to him in the first instance and

then we had to arrange another meeting because he had to leave for me to actually get the signature on the letterhead.

Now having provided him with the draft which was not on letterhead, what did you see him do with it?---He made no changes.

He was completely happy, was he, with what you prepared - - -?---Yes, that's correct.

10 - - - for him to sign?---Yes.

And having obtained that understanding from him what then occurred so as to have the letter presented on the letterhead of North Sydney Health?---He, he left, he said we'll have to come back for the next meeting because I have to leave because he couldn't wait for me to go and print, I printed this on this letterhead.

And where did you get the letterhead from?---It's available openly.

20 What does that mean?---That means it's available in a tray at the Kolling building.

THE COMMISSIONER: You can just go and walk up and take it?---Yes. They're available in a tray. There's a stack of that because I was using them to print the Patient Ethic, the Patient Consent Forms on.

So any member of the public can come up and take it?---Oh, well, not in the Kolling building because you need swipe access from level 8 and above but level 7 and below, anyone can walk in.

30 Are you saying you didn't have to anyone if you could use it?---No, that's also with all the other hospitals as well, they're in a tray.

You can just take their letterheads and use them?---Yes, there isn't - - -

You don't have to get permission from anyone to do that?---There is no supervision of where the letterheads are kept.

40 MR ALEXIS: All right. Anyway, you obtained the letterhead, from what level of the Kolling building did you say?---Level 8.

Level 8, that needs security access doesn't it?---Yes, I have security access for level 8.

So what the Commissioner said about public access doesn't apply to level 8?---That's what I'm saying, level 8 and above you need swipe access, level 7 and below anyone can walk in.

But you procured this letterhead from level 8?---That's right, that's where my cubicle was and that's where my desk is where I sat.

And you were able to do that because you had swipe access to that secured area?---That's correct.

Thank you. Now, you have the letter then printed on the letterhead of North Sydney Health. What did you then do with it?---I waited 'til the next meeting was which was a few days later.

10

Ah hmm. And what happened then?---And it was printed on the day that he signed that. I waited until he arranged for the next meeting.

So your evidence is that Dr Vaux signed this letter on the date of the letter, 12 June?---Yes, of course, yes.

And where did he sign it?---Sorry?

20

Where did he sign it? I don't mean where on the letter, I mean where physically was he when he signed the letter?---Oh, up in the cafeteria.

Right. This was another cafeteria meeting was it?---They were all cafeteria meetings.

And he signed the original letter?---Yes.

Did he sign a copy as well?---He signed two originals.

30

Ah hmm?---One original that you got from, the ICAC got from my folder and the other original was posted to the given address up there, by then Medex had changed their name but the address is the same I think, I'm not quite sure, it's the same people.

So, and once you got the original letter signed what did you do with it?---I kept one, a copy and I posted the other copy to the given address.

And insofar as ethical approval is concerned I gather nothing had changed up to 12 June?---Nothing had.

40

You hadn't submitted the application?---No, because - - -

No approval, no approval had been obtained?---No, no, I was still waiting for them to get back to me which I voiced to both at that time because Professor Ross Smith was like how's the application going and I'm still waiting on updates and changes from the people I've given, now given them to.

Now the study referred to in this letter of course wasn't a pilot was it - - -?

---No.

- - - because it involved 200 patients?---That's correct.

As the letter would indicate?---That's correct.

10 And you say do you that Professor, let me withdraw that. You say that Dr Vaux was completely accepting of the idea of conducting a significant study of 200 patients without obtaining ethical approval?---That's correct. He had no objection to it when that letter was submitted. He didn't even make any changes.

All right. Now, approximately when prior to 12 June 2009 did you undertake the examination of the 200 patients?---Once I met him and I was given approval. That was before he signed my supervision form and he told, he showed me and told me where I needed to go and he said go ahead with it. I can't tell you the exact month or date but around, like before he signed my supervision form.

20 Well, you told me earlier that you spoke to him initially on the telephone, Dr Vaux?---That's correct.

You then had - - -?---But that was to arrange the meeting.

You then had the cafeteria meeting which we described as the first meeting? ---Yes.

30 Then you tell me there were subsequent meetings in the cafeteria?---That's correct and on one of those meetings he took me to the clinic and showed me around and - - -

Well, when between the, the first meeting in the cafeteria and 12 June did you examine 200 patients?---Throughout the, as soon as he said go ahead with it.

Well, during what months of 2009?---We would have started in 2008.

40 All right. So your evidence is that from when, December 2008 through until - - -?---No, earlier, earlier than, earlier than December 2008.

All right. Well, can you try and give me as clearly as you can the approximate commencement date and the approximate end date of the testing that was done with respect to the 200 patients referred to in this letter?---I can't give you an exact month or an approximation. Like I said, it would have been a significant time, like a month or two before my supervision form that he signed.

THE COMMISSIONER: I beg your pardon?---It would have been a month or two before he signed my supervision form.

He being, Dr - - -?---Vaux.

Dr Vaux?---Vaux.

10 MR ALEXIS: Now madam, I want to ask you some questions about the invoices and the non-order vouchers that were submitted at Royal North Shore which are reproduced from page 206 and following of the examination bundle. And can I just understand perhaps at this stage without going to each, whether every invoice from Medical and Clinical Informatics Consultants and Wish Consulting and Complete Health and Medicine that are reproduced in the bundle were prepared by you and submitted by you to the Royal North Shore Hospital for payment?---That's correct.

The Wish Consulting invoices, may we take it were prepared in collaboration with your sister, Michelle?---Yes, we worked on that together.

20 So she was well understanding of what was claimed in each invoice, the amount that was claimed in each invoice and that you were submitting that invoice on behalf of her company for payment?---That's correct.

Now in relation to the invoices for the examination tests. Should we understand that the invoices which describe cervical cancer screening as being invoices relating to the patients of Professor Burton?---That's correct.

30 And if we illustrate by way of example the invoice at page 227 on behalf of Complete Health and Medicine, we see, pardon me, an invoice for the, for goods and services for clinical research and in the box we see a reference to cervical cancer screening?---That's correct.

And so we should understand that as a reference to Professor Burton's patients?---Correct, yes.

And we should understand that in relation to all of the other invoices that are similarly described, for example, the invoice at page 229?---Yes, I see - - -

40 Is that right?---I see what you're saying, it's just I haven't made the changes and I've just left it as it is.

All right. Now in relation to - - -

THE COMMISSIONER: Mr Alexis - - -

MR ALEXIS: I'm sorry?

THE COMMISSIONER: Is this a convenient time to adjourn?

MR ALEXIS: Yes, although I see my learned friend wishes to raise something, so while we have the moment, perhaps she ought to raise it now.

MS SOARS: I think, I think it would only be fair to my client that each invoice is put to her and she is asked about it respect of cervical cancer screening.

- 10 MR ALEXIS: I see. All right. Commissioner, can I just raise, before we adjourn, Professor Smith is here, has been, I think waiting patiently for most of the morning, I'm in a position to indicate that I could call him immediately after the luncheon adjournment, having regard to the remaining handful or so of topics that I have for Ms Lazarus.

THE COMMISSIONER: Yes, all right.

MR ALEXIS: If that's perhaps a convenient course for him.

- 20 THE COMMISSIONER: Now, are we going to finish Professor Smith this afternoon?

MR ALEXIS: I would hope so.

THE COMMISSIONER: Do we need to start early?

MR ALEXIS: Could I just ask my learned friend a question? Perhaps we could start a little earlier if it's not inconvenient.

- 30 THE COMMISSIONER: Quarter to 2.00.

MR ALEXIS: Thank you, Commissioner.

LUNCHEON ADJOURNMENT

[1.01pm]