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IN THE COURT OF COMMON PLEAS

CUYAHOGA COUNTY, OHIO

MARY LOU ZIMMERMAN,
et al.,

Plaintiffs,

JUDGE BURNSIDE
CASE NO. 399411

-vs-

CLEVELAND CLINIC FOUNDATION,
et al.,

Defendants.

Deposition of ALAN E. LICHTIN, M.D., taken as if
upon cross-examination before Laura L. Ware, a
Notary Public within and for the State of Ohio, at
The Cleveland Clinic Foundation, 9500 Euclid Avenue,
The Taussig Cancer Center, Room R2-030, Cleveland,
Ohio, at 9:35 a.m. on Wednesday, December 5, 2001,
pursuant to notice and/or stipulations of counsel,
on behalf of the Plaintiffs in this cause.

WARE REPORTING SERVICE
21860 CROSSBEAM LANE
ROCKY RIVER, OH 44116
(216) 533-7606 FAX (440) 333-0745

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APPEARANCES:

Robert F. Linton, Jr., Esq.
Linton & Hirshman
Hoyt Block Building - Suite 300
700 West St. Clair Avenue
Cleveland, Ohio 44113
(216) 771-5800,

- and -

Mark W. Ruf, Esq.
Hoyt Block Building - Suite 300
700 West St. Clair Avenue
Cleveland, Ohio 44113
(216) 687-1999,

On behalf of the Plaintiffs;

Alan Parker, Esq.
Reminger & Reminger
113 St. Clair Building
Cleveland, Ohio 44114
(216) 687-1311,

On behalf of the Defendant.

ALSO PRESENT:

Michael J. Meehan, Esq.

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MR. PARKER Let's go on the record
before we call the doctor, if we can. This is
Alan Parker, Counsel for Cleveland Clinic
Foundation. Today, December 5th, in response
to the Plaintiffs' sixth request for production
of documents, request number two, The Cleveland
Clinic Foundation provided for inspection a
copy of the Institutional Review Board policies
and procedures which are in effect in the years
2000 and 2001.

We've done so in a spirit of
cooperation, despite our serious reservations
as to not only the relevancy of the
Institutional Review Board policies and
procedures for that date but even the more
expanded concept of relevancy that applies to
discovery inquiries.

These IRB policies and procedures were
not in effect at the time of Mrs. Zimmerman's
care and treatment or at the time of the
surgery. That is at issue in this case, and
thus it is a stretch to determine how this
policy and procedure manual would lead to
discovery of admissible evidence: however, we
provided it for inspection and indicated to

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counsel that if there were particular passages
that they desired they should mark those
passages and we would provide copies.

What counsel has done in response to
that is mark almost, not quite, but almost
every page of a document that I'm estimating is
about 200 pages in length. I believe that
there are 14 pages that were not marked, and
there is also a singular set of pages
constituting 15 pages that were not marked that
probably weren't marked simply because they're
accessible via Internet. There are Internet
addresses on those 15 pages.

Having said that, I think that what's
happening in this case, and particularly with
regard to this request, is that we're engaged
in a fishing expedition. We're engaged in
discovery that is not reasonably calculated to
lead to the discovery of admissible evidence,
and we therefore object to provide copies of
all these pages that have been marked.

Now, counsel has had an opportunity to
inspect, counsel will have this document
available during the course of this deposition
to ask questions that counsel believes are

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appropriate and I hope will be relevant to the subject matter and appropriate for discovery. However, with regard to the actual copying of this voluminous set of pages that have been requested, we'll place this document at the end of this deposition and present it to the Court for a ruling. The rule will be filed for protective order, so long as the request is as wide range and over broad as it appears as it's going to be.

I'll go get Dr. Lichtin for this deposition.

MR. LINTON: Thank you.

-- --

(Off the record.)

-- --

MR. LINTON: Just to respond, first of all, our request for production of documents also included in item one the policies, procedures and protocols in effect in 1998. Those, as i understand, have not been produced. In terms of the relevancy, we will explain to the Court at the appropriate time exactly how these are relevant to our case.

We have had only a 30-minute

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opportunity to inspect those. Given my schedule and Dr. Lichtin's schedule, i don't have the time at this point to engage in a detailed review of these documents which would probably take most of a day, and I agree that if there's any questions as to relevancy that that should be submitted to the Court for an in camera inspection.

I would further note that we have signed, prior to today, given to you at the start of the deposition, the confidentiality agreement that was provided to us to assure The Cleveland Clinic that this information which they allege to be proprietary and confidential would be used solely for purposes of this litigation and would be governed by the terms of the protective order. We can brief the additional issues with the Court.

MR. PARKER: Well, let me just also indicate that if Plaintiffs' counsel desires additional time to review this document in order to pear down the request, maybe to something that we can mutually agree is appropriate, then I'll be happy to schedule such an opportunity to do so, if we want to try

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and do that.

MR. LINTON: I think the fairest thing is to submit it to the Court and the court can make a determination about which of those documents you should be entitled to retain and which should be produced to us in discovery.

MR. PARKER: Okay. Thanks.

-- --

ALAN E. LICHTIN, M.D., of lawful age, called by the Plaintiffs for the purpose of cross-examination, as provided by the Rules of Civil Procedure, being by me first duly sworn, as hereinafter certified, deposed and said as follows:

CROSS-EXAMINATION OF ALAN E. LICHTIN, M.D.
BY MR. LINTON:

Q. Dr. Lichtin, good morning. My name is Bob Linton, and Mark Ruf and I represent the Zimmermans in a lawsuit that's been filed against The Cleveland Clinic Foundation. We have requested your deposition, and I appreciate you appearing here today to answer our questions.

If I say something that is unclear or that doesn't make sense to you, please stop me. I'm not here to try to confuse you. You and I tend to speak, doctors and lawyers, that is, speak in

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different languages, and if I say something that doesn't make sense please don't answer it. If you're confused in any way, please don't answer it, just ask for clarification so that we're on the same wavelength. Okay?

A. Yes.

Q. Will you also give verbal answers, like you've just done, because our Court Reporter can't take down nods or gestures?

A. Yes.

Q. Thank you. We have in front of us documents that have been produced by The Cleveland Clinic in response to our discovery requests. If you need to review any piece of this paper or any other paper before answering your question, please feel free to do so. This is an open book examination. Okay?

A. Yes.

Q. Have you ever had your deposition taken before?

A. Yes.

Q. Approximately how many times?

A. Twice.

Q. Were both of those in connection with your work on the IRB?

A. No.

Q. Were either of them in connection with your work on

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1 the IRE?
 2 A. No.
 3 Q. What were the issues in those other depositions;
 4 what was the subject matter of the other
 5 depositions?
 6 MR. PARKER: Objection. You can
 7 answer.
 8 A. A patient of mine was suing his place of employment
 9 because he felt he developed his hematologic
 10 disorder by exposure, so I gave a deposition in that
 11 case.
 12 The second one was a patient with an extremely
 13 rare fungal infection who died here, and we made the
 14 diagnosis very close at the point of death and so
 15 the family took action.
 16 Q. What have you done to prepare for your deposition
 17 today?
 18 A. I've talked to Mike Meehan and Mr. Marker.
 19 Q. Parker?
 20 A. Parker, yes, sorry. And that's it.
 21 Q. Have you reviewed any documents to prepare for your
 22 deposition?
 23 A. Not really.
 24 Q. Have you reviewed any in anyway, looked at
 25 anything?

10

1 A. I've not.
 2 Q. Handing you what has been marked as Plaintiffs'
 3 Exhibit 1, have you -- it's identified as
 4 Plaintiffs' sixth request for production of
 5 documents. Have you seen that document before?
 6 A. No.
 7 Q. Did you assist at all in obtaining records in
 8 response to our request for documents?
 9 A. I know Dan Beyer of our IRB office did.
 10 Q. And how do you spell Dan's name last?
 11 A. B-E-Y-E-R.
 12 Q. What is his position?
 13 A. He's the Executive Director of the IRB, mostly an
 14 administrative title.
 15 Q. What are his qualifications, what type of
 16 qualification does he have, is he a physician?
 17 A. No.
 18 Q. Did he assist in assembling these documents per your
 19 request?
 20 A. Not really.
 21 Q. Did you talk at all with him in connection with his
 22 attempt to respond to our request for documents?
 23 A. Yes.
 24 Q. Did you assist him in locating those documents; did
 25 you tell him where to look, what to find?

11

1 A. No.
 2 Q. What did the conversations consist of?
 3 MR. PARKER: Wait, objection. Answer
 4 if you can.
 5 A. You asked if I assisted him in locating? I did not
 6 assist him in locating anything.
 7 Q. Okay. What assistance did you provide?
 8 A. I discussed what was talked with me about and tried
 9 to recall any IRB records we might have had
 10 pertaining to this issue.
 11 Q. This issue being?
 12 A. The Zimmerman lawsuit.
 13 Q. The issue being psychosurgery?
 14 A. Yes.
 15 Q. And as part of the Cleveland Clinic's attempts to
 16 respond to our document request, you searched your
 17 own memory to think in your time on the IRB were you
 18 ever involved in cases involving psychosurgery; is
 19 that fair?
 20 A. Did we -- no.
 21 Q. How --
 22 A. I would ask the question did I remember any IRE
 23 evaluations of protocols relating to psychosurgery
 24 and the answer would be, yes, I did remember one.
 25 Q. And what study was that?

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1 A. It was a study by Susan Stagno and Dr. Hassenbusch
 2 from years ago. I do not remember the exact date,
 3 but that's the only one I remember.
 4 Q. Might there be others that occurred during your
 5 tenure that you simply could not recall presently?
 6 A. It's possible.
 7 Q. Can you give me some idea, an estimated range, of
 8 the number of projects you've evaluated in your
 9 tenure on the IRB?
 10 A. Well, I've been chairman since July 1, 1997, and
 11 I've been on the board since 1989. In all my years
 12 on the IRB there's probably been thousands of
 13 protocols that I've seen.
 14 Q. Thousands, plural?
 15 A. Yes, but that was the only one I remember.
 16 MR. PARKER: Pertaining to
 17 psychosurgery?
 18 A. Pertaining to psychosurgery.
 19 Q. And what did you -- did you tell Dan Beyer where he
 20 could look to try to obtain information about that
 21 study?
 22 A. No.
 23 Q. Where would you look if you were trying to find
 24 documents relating to any psychosurgery studies that
 25 have been submitted to the IRB for review?

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1 A. The IRB filing system is kept up to date in the IRB
2 office, and then things that become old get filed at
3 an off-site location. I don't know where those
4 are. I let Dan handle that.
5 Q. The files that are kept on location in the IRB
6 office, is that for -- strike that.
7 What is the record retention policy at the
8 Clinic for keeping IRB files?
9 A. I honestly don't know off the top of my head what
10 that policy is.
11 Q. Do you know if it's longer than the time period
12 required by the government of three years?
13 A. To be honest with you, I'm not sure. A question
14 like that, I would turn to Dan and I would say how
15 is our filing system.
16 Q. Not a problem. Not a problem. Handing you what's
17 been marked as Plaintiffs' Exhibit 8, have you seen
18 this document before I just handed it to you?
19 A. Yes.
20 Q. Whose handwriting is contained on that?
21 A. Honestly, I'm not sure. It might be Dan Beyer, it
22 might not be; I'm not sure.
23 Q. All right. What is this record?
24 A. I believe this is all that Dan could come up with
25 for this file. Now, I do remember this protocol

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1 coming to the board and I remember the discussions
2 generated, so there was a protocol, but Dr.
3 Hassenbusch and I spoke about it back at this time
4 frame.
5 Q. '89 to '94?
6 A. It must have been '89, but this was all we could
7 find.
8 Q. I want you to take your time and tell me what you
9 can remember presently about this study.
10 MR. PARKER: Objection. That's an
11 awfully vague and ambiguous question, but you
12 can try and tackle it, Doctor, if you
13 understand it.
14 A. Repeat the question.
15 Q. Sure.
16 - - - -
17 (Thereupon, the requested portion of
18 the record was read by the Notary.)
19 - - - -
20 A. I remembered that it seemed dramatic to alter one's
21 behavior by surgery, so I forget if Dr. Hassenbusch
22 actually came to a meeting or I talked to him about
23 it away from a meeting, but it was a brief
24 conversation, and I'm actually trying to remember if
25 it was Hassenbusch or Dr. Stagno. I honestly just

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1 remember a discussion I might have had, you know,
2 eleven years ago that was probably about a minute or
3 two minutes long and just the idea that this type of
4 procedure might occur and might help people.
5 Q. It was dramatic, in your experience?
6 A. My -- yeah. I have no experience with this
7 personally.
8 Q. Had you been aware of any type of surgery like that
9 being performed before this study was presented to
10 you?
11 A. All I remembered was from medical school reading
12 about frontal lobotomies back in the '50s.
13 Q. And in '89 you would have then been vice chair of
14 the IRB?
15 A. I don't think so. I was vice chair like '95, '96.
16 It's probably on my CV. I don't remember. It
17 probably doesn't even say vice chair. It probably
18 says I was chairman in '97.
19 Q. Handing you what's been marked as Exhibit 9, first
20 of all, is that a current copy of your CV?
21 A. Yes.
22 Q. Looking at page three --
23 A. Yeah, this is not accurate. I mean, I was not first
24 vice chair from the moment I got on the board. It
25 was in '95 or '96. I'd have to look back in my old

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1 copies of CVs to tell you for sure.
2 Q. To clarify, you would not have been vice chair at
3 the time the Stagno study was presented?
4 A. I strongly do not think I was.
5 Q. Do you recall actually being a participating IRB
6 board member at the time this study came before the
7 board?
8 A. I'm sure I was, yeah.
9 Q. All right. Based on your memory and your experience
10 with the practice back then, what would be involved
11 in submitting a study like this to the IRE?
12 A. A --
13 MR. PARKER: Before you answer, let me
14 just enter an objection even into inquiry about
15 a study that wasn't involved in the Zimmerman
16 case and has nothing to do with the Zimmerman
17 case. Having done so, go ahead and answer the
18 question.
19 A. The principal investigator would write up a protocol
20 which would have an introduction, you know,
21 scientific validity statements and statistical
22 analysis and a plan of action, methods for, you
23 know, tracking adverse events, everything would have
24 to be in the protocol. And then there would be a
25 consent form with all the elements of informed

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1 consent present. The board would review it, it
 2 would either table it or pass it or reject it.
 3 Q. Are the investigators or co-investigators involved
 4 in presenting that to the board?
 5 A. Usually not.
 6 Q. So it's a written submission?
 7 A. Usually.
 8 Q. And minutes are kept of the IRB meetings, are they
 9 not?
 10 A. Uh-huh, yes.
 11 Q. Thank you. Do you know what the record retention
 12 policy is here at the Clinic?
 13 A. I honestly don't know.
 14 Q. For board minute meetings?
 15 A. I don't know.
 16 Q. Board meeting minutes.
 17 A. That is the type of question I would turn to Dan
 18 Beyer and ask him.
 19 Q. Did Dan Beyer work in his position back in the late
 20 '80s?
 21 A. No.
 22 Q. Do you know who had that position?
 23 A. Late '80s -- we did not have an executive director
 24 of the IRB until 1999.
 25 Q. Who would have served in that capacity; who would

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1 have done those responsibilities?
 2 A. We really didn't have that position. We had
 3 secretaries.
 4 Q. Who was head of the IRB back in 1989?
 5 A. I believe it was Angelo Licata, L-I-C-A-T-A.
 6 Q. And what was his specialty?
 7 A. Endocrinology.
 8 Q. Were there any neurosurgeons or board members
 9 qualified in neurosurgical issues at the time the
 10 Stagno study was submitted to the IRB?
 11 A. In my remembrance, there's always been somebody on
 12 the IRB in the mental health field. I can't
 13 remember whether we had a neurosurgeon on at that
 14 time, but I know we had either a neuropsychology
 15 person or psychiatrist or someone related to mental
 16 health.
 17 Q. Was the submission ultimately approved by the IRB?
 18 A. I believe it was. It does say project period. That
 19 usually is terminology for an approval period.
 20 Q. This would not have been an FDA sponsored project,
 21 would it?
 22 A. I don't think so, and I don't remember.
 23 Q. What is cingulotomy, as you understand it?
 24 A. I really don't know. I did not ever know what a
 25 cingulotomy was.

19

1 Q. What were the results of -- strike that.
 2 What happened as a result of that study, was it
 3 published?
 4 A. I don't know.
 5 Q. Who would you go to to find that out?
 6 A. Probably Dr. Stagno or Dr. Hassenbusch. To be
 7 honest with you, I thought Dr. Hassenbusch was the
 8 principal investigator of this. When we found this
 9 sheet of paper, I saw Dr. Stagno's name.
 10 Q. Stagno?
 11 A. I was surprised because my remembrance was
 12 Hassenbusch was the one who was the PI, but I was
 13 wrong.
 14 Q. Stagno is a psychiatrist?
 15 A. Correct.
 16 Q. And Hassenbusch was a neurosurgeon?
 17 A. Correct.
 18 Q. Was written consent required as part of that study?
 19 MR. PARKER Objection.
 20 A. I honestly don't remember.
 21 Q. Have you ever approved a -- strike that.
 22 Has the IRB ever approved of a research study
 23 where written consent was not required for a
 24 surgical procedure?
 25 MR. PARKER Objection.

20

1 A. I honestly don't remember.
 2 Q. By law, for an IRB approved project, is not written
 3 consent required presently?
 4 MR. PARKER: Objection to inquiring as
 5 to requirements of conclusions of law from this
 6 physician. You can answer, if you know.
 7 A. Say the question again.
 8 Q. Sure. Is it your understanding that by law an IRB
 9 approved project that involves surgery requires
 10 written consent?
 11 MR. PARKER Objection.
 12 THE WITNESS: Should I answer?
 13 MR. PARKER: Yes.
 14 A. By federal regulations, IRBs that deal with research
 15 and surgery can use whatever criteria they feel is
 16 valid for the necessity of informed consent. I
 17 would think for something like surgery most times we
 18 would say there has to be a written informed
 19 consent.
 20 There is regulatory language that allows an IRB
 21 to waive the usual forms of written informed consent
 22 if certain stipulations are met, and we would take
 23 each on a case by case basis. There might be
 24 something that you would want to do that, you know,
 25 you would say was surgery but is really not surgery

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1 and the IRB in its mind would waive written informed
2 consent.

3 Q. Can we agree that brain surgery, where you are
4 destroying parts of the brain in an attempt to treat
5 something like OCD, is a type of surgery that would
6 require written consent?

7 A. Yes.

8 Q. And why is that?

9 A. I don't think that such a procedure would ever have
10 those sorts of stipulations for waiver of written
11 informed consent.

12 Q. And what's the purpose of having a written informed
13 consent?

14 A. The purpose of written informed consent, you would
15 have to ask the drafters of the 45 CFR 46 what the
16 purpose of written informed consent is, but my
17 interpretation of it is, you know, to have research
18 subjects be informed of what research they're about
19 to undergo.

20 Q. And it assures that they have been adequately
21 informed of the risks, benefits and alternatives to
22 the procedure?

23 MR. PARKER: Objection.

24 A. I would just refer you to the language in 45 CFR 46
25 about what elements of informed consent are

22

1 necessary.

2 Q. Well, informed consent is an important part of any
3 research project that comes before the IRB, isn't
4 it?

5 A. Correct.

6 Q. What is your understanding of what is required for
7 informed consent?

8 A. As stated in 45 CFR 46, there has to be information
9 on research, risks, benefits, alternatives, cost
10 considerations, aspects of voluntary participation,
11 something related to what to do in case of research
12 related injuries. I might be missing something, but
13 there's about ten elements that have to be covered
14 by research subjects in participating research.

15 Q. And what is the advantage to having that be in
16 writing as opposed to simply being verbally told to
17 a patient?

18 A. Say that question again.

19 Q. Sure.

20 - - - -

21 (Thereupon, the requested portion of
22 the record was read by the Notary.)

23 - - - -

24 A. I'm not sure that there's an advantage of writing or
25 verbal. The federal regulations criteria that IRBs

23

1 have to exercise, whether a written informed consent
2 is necessary or not, some written informed consent
3 documents are long and voluminous and some patients
4 may not understand everything there, but we, as the
5 IRB, try to make it as much in layman's language as
6 possible.

7 MR. PARKER: Let me just insert a
8 statement or comment or objection, however you
9 want to phrase it. I just want the record to
10 reflect that the conversation that has been
11 occurring over the last few minutes about
12 informed consent and written informed consent
13 are in the context of IRB review of research
14 activities.

15 MR. LINTON: I'm going to object and
16 move to strike that comment by counsel.

17 Q. Doctor, are you aware of any other psychosurgical
18 procedures which have been submitted at anytime
19 during your tenure to the IRB besides the Stagno
20 study?

21 A. To the present time?

22 Q. Yes.

23 A. Yes.

24 Q. And that's the Rezai study?

25 A. Yes.

24

1 Q. Any other psychosurgical procedures or studies that
2 have been submitted to the IRB, that you're aware
3 of, besides those two?

4 A. I can't remember any.

5 Q. Do you recall at any time -- strike that.

6 Do you know Dr. Gene Barnett, neurosurgeon?

7 A. I know him.

8 Q. Do you recall being involved at all in the IRB
9 review of his study performing psychosurgery on
10 terminal cancer patients to try to relieve pain?

11 A. I don't remember.

12 Q. I don't know if, in fact, it was submitted. I just
13 want to know if you have any recollection of that
14 issue or that study being submitted to the IRB?

15 A. No.

16 Q. Help me out just in terms of basics. Why is there
17 an IRB at The Cleveland Clinic?

18 A. Any medical facility that wants to do research has
19 to have an IRB.

20 Q. It's required by law?

21 MR. PARKER: Objection.

22 A. Yes.

23 Q. Why is that?

24 A. There are federal regulations that say this. I'm
25 not sure if that's a law or whether that's a federal

25

1 regulation.
2 Q. When I use the word law, I include a federal
3 regulation.
4 A. Okay.
5 Q. So an IRB is required by federal regulation at any
6 institution doing research, correct?
7 A. Yes.
8 Q. And the purpose of an IRB is to protect human
9 subjects that are involved in that research,
10 correct?
11 A. Involved in research.
12 Q. Right. And your --that's the ultimate purpose of
13 an IRB, correct?
14 A. That's the purpose of an IRB.
15 Q. Is to make sure that the subject matters are
16 protected during research?
17 A. The research subjects are protected.
18 Q. Okay. That is the people that are willing to
19 undergo the research project?
20 A. The people who are research subjects.
21 Q. Okay. The people that are going to be the guinea
22 pigs in a research project?
23 MR. PARKER: Objection.
24 Q. I mean, if we break it -- correct?
25 MR. PARKER: Objection to the

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1 inflammatory language. You can answer, if that
2 is a question that you can provide a fair
3 answer to.
4 MR. MEEHAN: If he can't answer, he
5 can't answer, Alan.
6 A. The IRB is designed to protect research subjects who
7 are undergoing research.
8 Q. And your job, as head of the IRB, among other
9 things, is to make sure that those subjects are
10 protected in the research?
11 A. Just repeat the question.
12 Q. Sure. Part of your job as head of the IRB is to
13 make sure those research subjects are protected in
14 the research?
15 A. Yes.
16 Q. And in fact, it's important that you act
17 independently of the institution that employs you,
18 correct?
19 A. Yes.
20 Q. The idea is that you are to act independently from
21 the interests of the institution in perhaps carrying
22 out that research?
23 MR. PARKER: Objection. What do you
24 mean he acts independently?
25 Q. Well, do you not understand the question, Doctor?

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1 A. I don't understand the question.
2 Q. Is there a conflict of interest that's inherent in
3 any research between the physician and the patient?
4 A. I don't understand what you mean.
5 Q. Isn't there an inherent conflict of interest between
6 a physician who's doing research and a patient who's
7 involved in that research because the patient's goal
8 is to get better and the doctor's goal may be
9 research oriented as opposed to treatment oriented?
10 MR. PARKER: Objection. I guess you
11 can answer whether you agree with that or not.
12 A. I can see that there are differences between a
13 doctor/patient relationship and a
14 researcher/ research subject relationship.
15 MR. LINTON: Do you have the policies
16 and procedures?
17 MR. PARKER: Just so the record is
18 clear, you have the policies and procedures.
19 MR. LINTON: Yeah.
20 Q. If a research -- strike that.
21 If a study is submitted to the IRB board and
22 it's beyond the expertise of the board members, the
23 board has the authority to go outside the board to
24 obtain additional ad hoc review, if necessary; isn't
25 that true?

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1 A. Yes.
2 Q. So whenever the IRB feels, for whatever reason,
3 they're not qualified, they can get those qualified
4 to review the project, correct?
5 A. Repeat the question again.
6 - - -
7 (Thereupon, the requested portion of
8 the record was read by the Notary.)
9 - - -
10 A. Yes.
11 Q. So if -- did the Clinic go outside its then
12 constituted IRB to obtain experts on an ad hoc basis
13 to review the Stagno study?
14 MR. PARKER: Objection. If the
15 question is regarding the Stagno study, you can't
16 answer.
17 A. I honestly don't remember.
18 Q. Is one of the purposes of the IRB to also approve
19 the research protocols that are submitted?
20 A. Say it again.
21 Q. Sure. What are the responsibilities of the IRB?
22 A. To oversee research.
23 Q. Does that include approving research protocol?
24 A. Yes.
25 Q. Does that include making sure that there is a

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- 1 scientific foundation for the research?
- 2 A. Yes.
- 3 Q. That the study is valid, the study --
- 4 A. I would say --
- 5 Q. The research protocols are valid?
- 6 A. Yes.
- 7 Q. And that the statistical analysis is correct?
- 8 A. Correct.
- 9 Q. And if, for whatever reason, it is incorrect, the
- 10 IRB can make recommendations that it be changed
- 11 before approval is given, correct?
- 12 A. Correct.
- 13 Q. And you're familiar with statistics, are you not, as
- 14 part of your education, training and experience?
- 15 A. I am not a board certified statistician. I have a
- 16 rudimentary understanding of statistics.
- 17 Q. You certainly know enough in order to approve the
- 18 research protocol that's submitted to the IRB?
- 19 A. Oftentimes I will turn to other members of the IRB
- 20 who know more about statistical design to get their
- 21 input.
- 22 Q. Well, for example, in your own practice you have a
- 23 specialty in oncology?
- 24 A. Hematology/oncology.
- 25 Q. And if there's a new form of cancer that's out there

30

- 1 which some people are treating by radiation and
- 2 there's a certain success rate for that, and there's
- 3 others that are being treated by chemotherapy and
- 4 there's a certain success rate for that, you can't
- 5 just simply combine those two therapies and mix and
- 6 match the statistics, can you?
- 7 MR. PARKER: Objection.
- 8 Q. Is that Statistically valid?
- 9 A. I don't know how to answer something like that.
- 10 Q. Why is that?
- 11 A. Because this is a very hypothetical circumstance.
- 12 Q. I'm asking hypothetically.
- 13 MR. PARKER: And I think he just
- 14 indicated he can't answer that.
- 15 Q. And if there was a study, for example, in your field
- 16 that showed chemo had a 30 percent success rate and
- 17 radiation had a, let's say, 40 to 50 percent success
- 18 rate, you couldn't simply say to a patient, well,
- 19 I'll give you both and get a 75 percent success
- 20 rate, could you?
- 21 MR. PARKER: Objection.
- 22 A. I have no way to be able to answer a question like
- 23 that. It's hypothetical.
- 24 Q. I know it's hypothetical. Are you saying that would
- 25 be statistically valid to make that statement?

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- 1 MR. PARKER: No, he said he can't
- 2 answer that question. Now, if you want to ask
- 3 it --
- 4 Q. Would that be a statistically valid statement?
- 5 A. I can't answer that. I don't know enough about
- 6 statistics to say.
- 7 Q. Well, do you recommend treatment for your own
- 8 patients?
- 9 A. Uh-huh, yes.
- 10 Q. And when you do that, do you quote statistics for
- 11 treatment based on your understanding of valid
- 12 studies and reports and literature?
- 13 A. I do.
- 14 Q. Do you ever quote statistics to patients when there
- 15 are not success rates that have been published in
- 16 the literature or subject to reliable studies?
- 17 A. No.
- 18 Q. Why not?
- 19 A. I'm guided by the reliable studies.
- 20 Q. You don't just independently add up statistics from
- 21 different reliable studies and present those to the
- 22 patient, do you?
- 23 MR. PARKER: Objection.
- 24 A. Say the question again.
- 25 Q. Sure. If there was a study that you relied on for

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- 1 one form of treatment with a statistic and a study
- 2 showing another different type of treatment with a
- 3 different statistic, would you simply combine those
- 4 two treatments for a patient when that had not been
- 5 subject to a reliable study or reports in the
- 6 literature?
- 7 A. Again --
- 8 MR. PARKER: Objection.
- 9 A. -- it's hypothetical. I don't see how I can answer
- 10 that question.
- 11 Q. Have you ever done that in your practice?
- 12 A. Cancer and hematology -- in cancer patients and
- 13 hematology patients we don't -- we're not confronted
- 14 by this type of question.
- 15 Q. You're not confronted with questions regarding
- 16 treatment and what are the best treatment options
- 17 for your patients?
- 18 A. We are.
- 19 Q. And you're not involved in trying to recommend
- 20 different treatment options to a patient?
- 21 A. We do.
- 22 Q. And when you do that, you base it on statistics as
- 23 reported in the literature or reliable studies?
- 24 A. Correct.
- 25 Q. As chairman of the IRB, would you approve a

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1 procedure for which there were no reported success
 2 rates or which had no reports in the literature?
 3 MR. PARKER: Objection. Calls for
 4 speculation.
 5 A. Say the question again.
 6 Q. Sure.
 7 - - - -
 8 (Thereupon, the requested portion of
 9 the record was read by the Notary.)
 10 - - - -
 11 A. As chairman of the IRB, I never approve something
 12 myself. It's up to the whole board to approve
 13 something.
 14 Q. Would you recommend its approval? You get a vote,
 15 do you not?
 16 A. I do.
 17 Q. Would you vote for its approval?
 18 MR. PARKER: Objection. The
 19 foundational question remains speculative. You
 20 can answer it, if **you** can do **so**.
 21 A. What was the foundational question again?
 22 - - - -
 23 (Thereupon, the requested portion of
 24 the record was read by the Notary.)
 25 - - - -

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1 A. Yes.
 2 Q. Under what circumstances?
 3 A. We would have to see a protocol, we'd have to see
 4 what medical knowledge there was leading up to the
 5 point of the protocol, we'd have to see the rest **of**
 6 the protocol to make a decision whether to approve
 7 it.
 8 Q. How do you define research in terms of what falls
 9 within IAB review?
 10 A. There's a definition of research, which I was hoping
 11 to memorize, but it's in here. It's systematic
 12 investigation. It's --
 13 Q. Are you looking for the definition section?
 14 A. There's some sheets that come after this. Maybe
 15 it's -- **it's in 45 CFR 46. Give me that.**
 16 MR. MEEHAN: This is my document. I'm
 17 a lawyer.
 18 A. It's not in here. You took it away. There was
 19 something behind here earlier this morning.
 20 MR. PARKER: It's in the CFR?
 21 A. CFR 45, 46. Systematic investigation designed to
 22 lead to generalizable knowledge. But there's some
 23 other subclauses in there which I can't remember off
 24 the top of my head, and I would feel more
 25 comfortable having it in front of me.

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1 I've got it. Research means a systematic
 2 investigation, comma, including research,
 3 development testing and evaluation designed **to**
 4 develop or contribute to generalizable knowledge.
 5 Q. Can there be treatment that **is** also research?
 6 A. There's no definition of treatment. There's only
 7 the definition of research.
 8 Q. Would you agree that if there **is** any element **of**
 9 research that -- when do experimental treatments
 10 fall within the jurisdiction **of** the IRB?
 11 A. Research falls under the jurisdiction of the IRB.
 12 Q. Well, can there be experimental procedures that are
 13 done both for the patient's benefit as well as
 14 contribute to the generalized medical knowledge?
 15 MR. PARKER: Objection to the term
 16 experimental.
 17 A. I think that question puts terms together which
 18 makes it impossible for me **to** answer the question.
 19 Q. Well, what safeguards are in place at The Cleveland
 20 Clinic to make sure that experimental procedures,
 21 surgical procedures, are not being performed on
 22 patients?
 23 MR. PARKER: Objection.
 24 A. Newer techniques or innovative surgical procedures
 25 are done. If they're not researched, they don't

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1 come to the IRB.
 2 Q. And who oversees those new or innovative procedures
 3 before they're being performed on a patient?
 4 A. Doctors who are surgeons that discuss among
 5 themselves what -- and they have department chairs
 6 who look over what is done in each department, **so**
 7 we, at the IRB, try to disseminate the message of
 8 what research is.
 9 Q. **How do** you do that?
 10 A. All the research application packets have the, you
 11 know, definitions and have where physicians can cite
 12 reference to these definitions. We have ongoing
 13 educational efforts.
 14 Q. Has there ever been any sort of psychosurgical
 15 review **board here** at **The Cleveland Clinic, to your**
 16 knowledge?
 17 A. I don't know.
 18 Q. **Is** there any institutional check in place on
 19 experiments with individual patients?
 20 MR. PARKER: Objection.
 21 A. Again, you're using a term which --
 22 Q. Which term is that?
 23 A. Experimental, which is not the same as research.
 24 Q. I understand that.
 25 MR. PARKER: And let me just also note

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1 an objection. You're asking him for any
 2 institutional -- I forget your term, any
 3 institutional whatever. Dr. Lichtin can only
 4 speak for areas, obviously, in which he's
 5 knowledgeable. He can't speak for the
 6 institution.
 7 MR. LINTON: I understand.
 8 Q. Are you aware of any institutional safeguards to
 9 protect patients from any surgical procedures?
 10 MR. PARKER: Objection.
 11 A. I don't know how to answer that. I'm not aware
 12 of -- I don't know how to answer that.
 13 Q. Why don't you know how to answer it; is it confusing
 14 to you?
 15 A. I'm not confused.
 16 Q. Are there medical practices committees set up to
 17 approve and safeguard against experimental surgery
 18 here at Cleveland Clinic?
 19 MR. PARKER: Objection.
 20 A. I don't know.
 21 Q. Are you aware of any?
 22 A. I know there are committees that look at surgical
 23 practice, but I'm not aware of anything like what
 24 you're describing.
 25 Q. That is any committee that would approve an

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1 experimental surgical procedure before it's
 2 performed on a patient?
 3 MR. PARKER: Objection.
 4 Q. You're not aware of that?
 5 MR. PARKER: Go ahead and answer the
 6 question.
 7 A. No, I'm not aware of it.
 8 MR. PARKER: And may I ask what you
 9 mean by experimental procedure?
 10 Q. Experimental procedure, one that is for which there
 11 has been no scientifically valid study nor reports
 12 in the literature.
 13 MR. PARKER: Okay. That's not a
 14 question, but I want a clarification for the
 15 purposes of this record as to what you mean.
 16 Q. What do you understand experimental procedure to
 17 mean?
 18 A. Well, I feel I have an understanding of research.
 19 Q. Okay.
 20 A. But if a doctor, in his or her practice of medicine,
 21 wants to try something on a patient that does not
 22 mean that's research. You may call that
 23 experimental, but the doctor may view that as his
 24 practice of medicine.
 25 Q. Well, are there any guidelines available to

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1 determine whether it is experimental or not?
 2 A. There are guidelines that determine the definition
 3 of research.
 4 Q. In your judgment, is research different than
 5 experimentation?
 6 MR. PARKER: Objection. I think a part
 7 of the problem here is he has said again and
 8 again and again that the term experimentation
 9 is not a term that has a specific meaning to
 10 him, so I don't know how he can answer your
 11 question. If you can answer it, feel free to
 12 do so.
 13 A. No.
 14 Q. Are there ever times that innovative therapies are
 15 submitted to the IRB for approval?
 16 A. When the innovative therapies are a part of a
 17 research protocol they can be, they are, yes.
 18 Q. So if a doctor is doing innovative therapy that he
 19 also wants to study, then that's something that
 20 would be submitted to the IRB?
 21 A. Correct.
 22 Q. And that would then require all the IRB safeguards
 23 to be followed?
 24 A. Correct.
 25 Q. And make sure that there is a scientifically valid

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1 basis for the research, correct?
 2 A. Correct.
 3 Q. As well as to make sure that the subjects of that
 4 innovative therapy are protected?
 5 A. Correct.
 6 Q. Should psychosurgery at The Cleveland Clinic be
 7 subject to IRB review?
 8 A. If it's research, yes.
 9 Q. What if it -- in order for it to be researched, does
 10 it have to be published?
 11 A. No.
 12 Q. Does it have to be reported?
 13 A. No.
 14 Q. Does a study even have to be concluded?
 15 A. No,
 16 Q. Is there a limited number -- strike that.
 17 Is there a minimum number of patients that have
 18 to be studied in order for it to be researched?
 19 A. No.
 20 Q. Can there be research on a single patient?
 21 A. Yes.
 22 Q. Who decides if it's research?
 23 A. The physician who is about to do the procedure, if
 24 the intention is that this is research and I want to
 25 contribute to generalizable knowledge, they would

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1 have to submit to an IRB. if the physician decides
 2 I just want to treat this one patient in what they
 3 feel is an innovative but potentially helpful way,
 4 it's up to the physician and they don't have to come
 5 to IRB.
 6 Q. And if there are mixed motives, should the physician
 7 err on the side of submitting it to the IRB for
 8 approval?
 9 MR. PARKER: Objection to form.
 10 A. if there's any hint of an intention to do research,
 11 it has to come to the IRB.
 12 Q. So the answer to my question is yes?
 13 A. You used the word mixed motives. I would say if
 14 there's an intention to do research.
 15 Q. In any --
 16 A. If any part of the consideration of the doctor is
 17 that they are about to propose research, then it
 18 should come to the IRB.
 19 Q. So that if there's a five percent intention to do
 20 research and --
 21 A. If there's a one millionth percent to do research.
 22 Q. It needs to come to IRB?
 23 A. It's an intention, in my mind.
 24 Q. Even if the doctor does not then have a present
 25 intention to publish the results of the research?

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1 A. I can foresee -- well, say the question again. I'm
 2 sorry.
 3 Q. Even if the physician at the time does not have a
 4 present intent to actually publish the results of
 5 the research? Bad question.
 6 MR. PARKER: Yeah.
 7 Q. If a physician wants to treat a patient with an
 8 experimental procedure and also wants to study the
 9 effectiveness of that experimental procedure, then
 10 that should be submitted to the IRB?
 11 MR. PARKER: Objection to the
 12 terminology. You can answer.
 13 A. Again, you're using the word experimental, and
 14 there's no regulatory definition of the word
 15 experimental.
 16 Q. Well, is there one for innovative?
 17 A. No.
 18 Q. Then why are you using the word innovative as
 19 opposed to experimental; is there some recognized
 20 definition for innovative?
 21 A. Not in 45 CFR 46.
 22 Q. If a doctor wants to use an innovative therapy both
 23 to treat his patient as well as to study the
 24 effectiveness of that innovative therapy, that
 25 should be submitted to the IRB for approval?

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1 A. If it's research, yes.
 2 Q. Well, research includes studying it to try to
 3 improve or contribute to generalized knowledge?
 4 A. I would say no.
 5 Q. Okay. What makes it research?
 6 A. It's the systematic investigation designed to
 7 contribute to generalizable knowledge. If someone
 8 wants to do an innovative surgical procedure and
 9 follow the patient to see how they do, that can fall
 10 under the term study the patient, but that's not
 11 research.
 12 Q. But if they want to study the effectiveness of the
 13 innovative therapy, should that not be done in a
 14 systematic fashion?
 15 A. Not necessarily.
 16 Q. Well, what does a physician have to do in order to
 17 do a valid study of an innovative therapy?
 18 A. Again, I think you're mixing terms. A research
 19 protocol has a certain design to it. An innovative
 20 surgical procedure where a doctor wants to study the
 21 effects of the surgery is not rigorous systematic
 22 investigation.
 23 Q. What is required for there to be a systematic
 24 rigorous investigation?
 25 MR. PARKER: I'm going to object. You

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1 can answer that, if you can answer it.
 2 A. A protocol, a research protocol.
 3 Q. Have any innovative therapies been submitted to the
 4 IRB for approval, in your experience, that do not
 5 involve research?
 6 A. I can't remember a specific instance, but people
 7 have submitted things to the IRB and we've reviewed
 8 it and said this is not research and therefore we
 9 don't have jurisdiction. I can't even give you an
 10 example, but I believe that's occurred.
 11 Q. What is done to check the science or the medicine of
 12 the proposed research when it's submitted to the
 13 IRB?
 14 A. There's enough scientific expertise around the table
 15 that can handle most things. If we are unsure of
 16 the science, we will ask for other doctors at the
 17 Clinic to look at it.
 18 Q. So you'll go beyond the science that's submitted by
 19 the physician?
 20 A. Yes.
 21 Q. To independently verify that?
 22 A. Yes.
 23 Q. And would you allow a procedure which -- strike
 24 that. Would you approve an IRB-- strike that.
 25 MR. PARKER: While you formulate your

45

1 question, why don't we take five minutes.
 2 We've been at it an hour.
 3 MR. LINTON: Sure.
 4 - - -
 5 (Thereupon, a recess was had.)
 6 - - -
 7 Q. Dr. Lichtin, you're familiar with The Cleveland
 8 Clinic's IRB policies and procedures, correct?
 9 A. If I had a question, I'd look it up.
 10 Q. But you've worked with the policies and procedures
 11 of the IRB throughout your tenure on the board,
 12 correct?
 13 A. From '99 on, yes.
 14 Q. You didn't review them before '99?
 15 A. We didn't have them before '99.
 16 Q. What did the IRB follow in making its decisions if
 17 there were no policies and procedures in place
 18 before '99?
 19 A. We followed the CFR 45, 46 and FDA regulations. We
 20 used the regulatory language that was disseminated
 21 by the federal authorities. Most everything here is
 22 a reiteration of those regulations anyway.
 23 Q. Was the Belmont report also something that was
 24 followed by the IRB before there were formal
 25 policies and procedures?

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1 A. The Belmont report is an expression of ethics, and
 2 we certainly agreed to what it says.
 3 Q. It's something --
 4 A. But it doesn't have regulatory teeth.
 5 Q. But it's something that you certainly would consult
 6 and acknowledge as a guideline or authority in
 7 helping to resolve ethical issues in an IRB
 8 context?
 9 A. Correct.
 10 Q. So I'm clear, there was not an IRB policy and
 11 procedure manual in place in 1998, correct?
 12 A. Not to my remembrance.
 13 Q. Does your policy and procedure manual allow for IRB
 14 review of anything beyond research as defined in the
 15 CFR?
 16 A. I don't think so. I'd have to look it up. I don't
 17 think so.
 18 Q. The Stagno study of cingulotomy was completed in
 19 1994, correct?
 20 A. Uh-huh, yes.
 21 Q. And that was for cingulotomy and the treatment of
 22 intractable OCD?
 23 A. Yes.
 24 Q. If a physician wanted to research cingulotomy
 25 coupled with another surgical procedure like

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1 capsulotomy, that would have required another IRB
 2 review, correct?
 3 A. If it was research, yes.
 4 Q. And that would require, then, the IRB process --
 5 strike that, would require separate submissions to
 6 the IRB, correct?
 7 A. No.
 8 Q. What would a physician have to do to comply with the
 9 requirements of IRB review if he was studying
 10 cingulotomy plus another surgical procedure like
 11 capsulotomy to treat OCD?
 12 A. The investigator could amend a protocol so you can
 13 have an established protocol and just put an
 14 amendment to it as opposed to submitting a whole new
 15 protocol.
 16 Q. But an additional amended protocol at the very least
 17 would have to be submitted, correct?
 18 A. Correct.
 19 Q. And if a different physician wanted to study that,
 20 could he ride the coattails of the earlier study and
 21 simply follow an amended submission, or would it
 22 have to be a new submission?
 23 A. He or she could try to do that, but the IRB might
 24 look at that amendment and say this is a whole new
 25 protocol, you have to submit a whole new protocol.

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1 Q. And as part of the protocol, would the physician
 2 have to cite whatever research then existed in the
 3 literature for the proposed procedures?
 4 A. Yes.
 5 Q. And those would be reviewed by the board to make
 6 sure they were accurate?
 7 A. By IRB, yes.
 8 Q. And if IRB didn't have any expertise among the board
 9 to review that, that could be assigned to somebody
 10 else with the necessary expertise, correct?
 11 A. Correct.
 12 Q. And there was no amended study submitted to the IRB
 13 combining cingulotomy with capsulotomy, correct?
 14 A. I have no idea. I don't know.
 15 Q. Do you remember any such study being submitted?
 16 A. I don't remember.
 17 Q. And likewise, you're not aware of any extension or
 18 continuation of the '94 study to include combining
 19 cingulotomy and capsulotomy, are you?
 20 A. I have no recollection.
 21 Q. Were you involved in approving Dr. Rezai's study?
 22 MR. PARKER: Objection to the question
 23 regarding Dr. Rezai's study. It's not material
 24 in this case. You can answer the question.
 25 A. Which study do you mean?

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1 Q. The study identified on Exhibit 6.
 2 A. Yes.
 3 Q. What was your involvement?
 4 A. Chairman of the IRB.
 5 Q. And what did you do as chairman of the IRB to
 6 approve Dr. Rezai's study?
 7 A. I supervised the discussion about the protocol, we
 8 had the investigators come to the IRB to discuss the
 9 protocol in more detail.
 10 Q. Why is that?
 11 A. Because it's dramatic.
 12 Q. In what way?
 13 A. The same way as I was talking about how dramatic the
 14 previous one was.
 15 Q. Dramatic in terms of doing anything -- strike that.
 16 How is this dramatic like the cingulotomy?
 17 A. Involved with neurosurgery for a psychiatric
 18 disease.
 19 Q. Did you review the original submission for Dr.
 20 Rezai's study?
 21 A. I remember looking at it. I forget who the primary
 22 reviewer was, but I do remember looking at it, yes.
 23 Q. And what materials were submitted in order to obtain
 24 IRB approval for Dr. Rezai's study?
 25 MR. PARKER: Let me reenter my

1 A. Correct.
 2 Q. And do you maintain copies of those records in your
 3 file?
 4 A. The IRB office does.
 5 Q. Is that Beyer again that would be in charge of that
 6 file?
 7 A. Correct.
 8 Q. Do you recall if there was any reference in the
 9 submission to other forms of neurosurgical treatment
 10 for OCD besides the electric stimulation?
 11 A. I don't remember. I would presume there would be.
 12 Q. Was there any consideration given to Dr. Rezai's
 13 study to the capacity of the patients to give proper
 14 informed consent in the sense that these were
 15 psychiatric patients, obviously serious psychiatric
 16 patients who would be considering neurosurgical
 17 treatment for their disorder?
 18 MR. PARKER: Objection.
 19 A. Yes.
 20 Q. And were there any additional safeguards that were
 21 provided because of that patient population?
 22 MR. PARKER: Objection.
 23 A. I believe so.
 24 Q. And what additional safeguards were implemented?
 25 MR. PARKER: Objection.

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1 objection regarding particulars of Dr. Rezai's
 2 study. Can I make that continuing so I'm
 3 not --
 4 MR. LINTON: Sure.
 5 A. I'd have to look back through the IRB records, but
 6 there was a protocol with it and there's a consent
 7 form, there was also -- there was a protocol and
 8 consent form.
 9 Q. Was it reviewed at more than one meeting?
 10 A. I don't remember. I'll bet it was.
 11 Q. Is the practice typically to have the submission
 12 reviewed and then, if necessary, follow up at
 13 another meeting with the investigator actually being
 14 present answering questions?
 15 A. Correct.
 16 Q. And there would be minutes of those meetings that
 17 would be recorded?
 18 A. Yes.
 19 Q. And are they transcribed or tape-recorded; how are
 20 they kept?
 21 A. We have an administrative staff member from the IRB
 22 office taking notes during the meeting and then she
 23 transcribes it.
 24 Q. And does she then circulate those to all the board
 25 members?

1 A. My remembrance is that there's a separate Committee
 2 of doctors to analyze the patient for whether
 3 they're likely to benefit and able to give consent.
 4 Q. And who is on that committee?
 5 A. I don't remember off the top of my head, but I think
 6 it's Dr. Agich who's the head of our bioethics
 7 department, Dr. Tesar who's the head of our
 8 psychiatry department. I think there are three, but
 9 I can't remember who they are.
 10 Q. And why is there a separate committee that reviews
 11 those patients for this type of procedure?
 12 A. Why is there a separate committee? From the IRB's
 13 perspective there's a separate committee because it
 14 was presented to us that way. I presume it's to be
 15 as sure as possible to protect the patient's
 16 welfare.
 17 Q. I want to go back to Dr. Rezai's study on Exhibit
 18 6. The study was first approved, according to that
 19 document, October 5th, 2001: is that right?
 20 MR. PARKER: Objection.
 21 A. I'd have to look back in our files, but that's what
 22 this says, yes.
 23 Q. What is this study information, by the way; what is
 24 this document?
 25 A. I believe this is just a way the IRB office has key

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1 dates to a project.

2 Q. The study number IRB 4498, that's the file number or

3 study number here?

4 A. Correct.

5 Q. Does that mean it's the 4,498th study?

6 A. I don't think so. There's a numbering system that

7 the IRB office has generated over the years, but

8 this is not the 4,498th study that the IRB has

9 done.

10 Q. Tell me what you can remember being discussed at the

11 board meeting when Dr. Rezai was there to answer

12 follow-up questions or concerns the IRB had about

13 his proposed study.

14 MR. PARKER Objection.

15 A. I remember many aspects of discussion pertaining to

16 FDA regulations, these electrodes and pacemaker, did

17 they comply with FDA criteria in getting an

18 investigative device exemption. I remember

19 discussion of the consent process, the determination

20 whether the patient is competent to give consent.

21 Q. What do you remember about the second topic, about

22 the consent process and what's required in terms of

23 the patient's competency to give consent?

24 A. I'd really have to look back at the file to get the

25 exact nature of what we said. I don't have our

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1 judgment about the project in front of me.

2 Q. What would you have to look to to find that, is that

3 the --

4 A. 4498, the file.

5 Q. Were there any discussions about the past results at

6 The Cleveland Clinic with psychosurgery?

7 A. I don't remember.

8 Q. Any discussion about past problems with

9 psychosurgery at The Cleveland Clinic?

10 A. I don't remember.

11 Q. Any discussions about the advantage of the electric

12 stimulation over conventional neurosurgery?

13 A. I honestly don't remember.

14 Q. Did Dr. Barnett, Gene Barnett, the neurosurgeon,

15 attend any of these IRB meetings?

16 A. Not to my remembrance, no.

17 Q. Have you ever had any discussions with him about

18 psychosurgery?

19 A. No.

20 MR. LINTON: Alan, is there some reason

21 why we haven't received all the other records

22 that were requested from Dr. Rezai's study?

23 MR. PARKER if there are other

24 records, I'll look into it for you.

25 Q. Well, what other records would exist, Doctor, for

55

1 Dr. Rezai's study?

2 A. A copy of his protocol.

3 Q. Minutes of the meeting --

4 A. Yes.

5 Q. --would exist?

6 A. Yes.

7 Q. What additional documents; correspondence?

8 A. Correct.

9 Q. You talked about your recommendation or your

10 judgment; is that contained in a separate document?

11 A. When I say recommendation or judgment, I mean

12 when we have certain things that we want them to

13 change that will be in a letter to the

14 investigator.

15 Q. Would there, likewise, be any research that would be

16 submitted: would that be part of the research

17 protocol?

18 A. Correct.

19 Q. There would be the written consent procedures and

20 written consent forms?

21 A. Correct.

22 Q. Any other documents that would be part of that

23 study?

24 A. My remembrance is there may be something

25 related to communications with the FDA about the

56

1 device.

2 Q. Anything else?

3 A. No.

4 Q. There, likewise, at one time would have been similar

5 documents with respect to the Stagno study,

6 correct?

7 A. I believe so.

8 Q. That would be research protocol, consent procedures,

9 written consent forms, correspondence and minute

10 meetings?

11 A. Correct.

12 Q. Excuse me, minutes of the meetings?

13 A. Correct.

14 MR. LINTON: Give us just a minute, if

15 you will.

16 - - - -

17 (Thereupon, a discussion was had off

18 the record.)

19 - - - -

20 MR. LINTON: Subject to additional

21 questions on the documents that we have not yet

22 received, and I think we'll probably be

23 fighting over, that's all the questions I have

24 at this time, Dr. Lichtin. Thank you very

25 much.

57

THE WITNESS: Okay.

MR. PARKER We'll read and sign.

ALAN E. LICHTIN, M.D.

58

CERTIFICATE

The State of Ohio) SS:
 County of Cuyahoga.)

I, Laura L. Ware, a Notary Public within and for the State of Ohio, do hereby certify that the within named witness, ALAN E. LICHTIN, M.D. was by me first duly sworn to testify the truth, the whole truth, and nothing but the truth in the cause aforesaid; that the testimony then given was reduced by me to stenotypy in the presence of said witness subsequently transcribed into typewriting under my direction, and that the foregoing is a true and correct transcript of the testimony so given as aforesaid.

I do further certify that this deposition was taken at the time and place as specified in the foregoing caption, and that I am not a relative, counsel or attorney of either party, that I am not, nor is the court reporting firm with which I am affiliated, under a contract as defined in Civil Rule 28(D), or otherwise interested in the outcome of this action.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed my seal of office at Cleveland, Ohio, this 11th day of December, 2001.


 Laura L. Ware, Ware Reporting Service
 21860 Crossbeam Lane, Rocky River, Ohio 44116
 My commission expires May 17, 2003.

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30:1</p> <p>treatment 3:20 27:9 31:7 31:11 32:1,2,16,16,20 35:5,6 46:21 51:9,17</p> <p>treatments 32:4 35:9</p> <p>tried 11:8</p> <p>true 27:25 58:10</p> <p>truth 58:7,8,8</p> <p>try 6:25 7:24 12:20 14:12 23:5 24:10 36:7 38:21 43:2 47:23</p> <p>trying 12:23 14:24 32:19</p> <p>turn 13:14 17:17 29:19</p> <p>Twice 8:21</p> <p>two 3:G 15:3 24:3 30:5 32:4</p> <p>type 10:15 15:3,8 17:17 21:5 32:2,14 52:11</p> <p>typewriting 58:9</p> <p>typically 50:11</p> <p>Uh-huh 17:10 31:9 46:20</p> <p>ultimate 25: 12</p> <p>ultimately 18: 17</p> <p>unclear 7:22</p> <p>under 34:2 35:11 43:10 58:9,14</p> <p>undergo 21:19 25:19</p> <p>undergoing 26:7</p> <p>understand 5:21 14:13 18:23 23:4 26:25 27:1,4 36:24 37:7 38:16</p> <p>understanding 20:8 22:6 29:16 31:11 38:18</p> <p>insure 44: 15</p> <p>until 17:24</p> <p>use 20: 15 25:2 42:22</p> <p>used 6:15 41:13 45:20</p> <p>using 36:21 42:13,18</p>	<p>usual 20:21</p> <p>usually 17:5,7 18:19</p> <p style="text-align: center;">V</p> <p>vague 14:11</p> <p>valid 20:16 29:3,5 30:8,25 31:4,11 38:11 39:25 43:17</p> <p>validity 16:21</p> <p>verbal 8:7 22:25</p> <p>verbally 22: 16</p> <p>verify 44:21</p> <p>very 9:14 30:11 47:16 56:24</p> <p>via 4:12</p> <p>vice 15:13,15,17,24 16:2</p> <p>view 38:23</p> <p>voluminous 5:4 23:3</p> <p>voluntary 22: 10</p> <p>vote 33:14,17</p> <p>vs 1:6</p> <p style="text-align: center;">W</p> <p>W 2:6</p> <p>Wait 11:3</p> <p>waive 20:21 21:1</p> <p>waiver 21:10</p> <p>want 6:25 14:8 20:24 23:5 23:9 24:13 31:2 38:14 40:24 41:2 43:12 52:17 55:12</p> <p>wanted 46:24 47: 19</p> <p>wants 24:18 38:21 39:19 42:7,8,22 43:8,20</p> <p>ware 1:12,21 58:6,20,20</p> <p>wasn't 16:15</p> <p>wavelength 8:5</p> <p>way 8:3 9:24 30:22 41:3 49:12,13 52:14,23,25</p> <p>Wednesday 1:16</p> <p>welfare 52: 16</p> <p>well 6:19 12:10 22:2 26:25 29:22 30:18 31:7 35:12,13,19 38:18,25 40:3 42:1,16,23 43:2,16 54:25</p> <p>were 3:18 4:1,8,10 8:22 8:25 9:3 11:17 12:23 18:8 19:1 33:1 45:17,24 48:6,21 49:23 51:14,20 51:20,24 54:5,22</p> <p>weren't 4: 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<p style="text-align: center;">3</p> <p>30 30:16 30-minute 5:25 300 2:3,7 333-0745 1:23 399411 1:6</p>			
<p style="text-align: center;">4</p> <p>4,498th 53:5,8</p>			

**IN THE COURT OF COMMON PLEAS
CUYAHOGA COUNTY, OHIO**

MARY LOU ZIMMERMAN, ETC.

Plaintiffs,

-VS-

**THE CLEVELAND CLINIC
FOUNDATION, et al.**

Defendants.

CASE NO. 399411

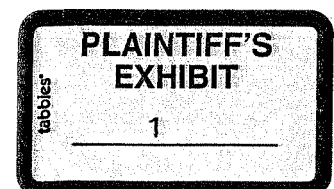
JUDGE JANET R. BURNSIDE

**PLAINTIFFS' SIXTH
REQUEST FOR PRODUCTION
OF DOCUMENTS**

Plaintiffs respectfully request Defendant The Cleveland Clinic Foundation to respond to the following Sixth Request for Production of Documents within twenty-eight days after receipt of this request, pursuant to the Ohio Rules of Civil Procedure 36. Pursuant to Civil Rule 26(E), these discovery requests are continuing.

REQUEST FOR PRODUCTION OF DOCUMENTS

Plaintiffs respectfully request Defendant to produce the following documents at the office of Robert F. Linton, Jr. and Mark W. Ruf, Hoyt Block, Suite 300, 700 West St. Clair avenue, Cleveland, Ohio, 44113, due within twenty-eight days after receipt of this request, pursuant to the Ohio Rules of Civil Procedure 34. Pursuant to Civil Rule 26(E), these requests are continuing. The Defendant, therefore, is requested to supplement these



requests with any additional documents which are uncovered after the documents below have been produced.

For the purposes of this request, the term "documents" refers to any document, notes, files, letters, writings, drawings, graphs, charts, photographs, records, slides, biopsies or tangible things relating directly or indirectly to the subject matter of the request.

If you object to the production of any document on the grounds that the request would be unduly burdensome, specify the exact actions necessary to produce such information, the most reasonable estimate or the amount of time involved in producing such records, the number of persons involved in the search for such records, the rate of pay for each such person, and each step you took to confirm the existence of such documents.

SIXTH REQUEST FOR PRODUCTION OF DOCUMENTS

1. All policies, procedures and protocols relating to the IRB and experimental surgical procedures performed at the Cleveland Clinic in effect in 1998.
2. All policies, procedures and protocols relating to the IRB and experimental surgical procedures performed at the Cleveland Clinic in effect in 2000-2001. This shall include, but not be limited to those relating to Dr. Rezai's current research project with Belgium, Brown University, and the Cleveland Clinic relating to neurosurgical treatment of OCD, as testified to at p. 33-35 of his deposition, attached as Exhibit A.;
3. Documents identifying all members of the IRB in 1998;
4. Documents identifying all members of the IRB in 2000-2001;
5. All documents relating to the IRB review of any psycho surgical procedures performed or considered at the Cleveland Clinic. This shall include, but not be limited to, lobotomy, cingulotomy, capsulotomy, combined cingulotomy and capsulotomy, and deep brain stimulation; and

6. A current curriculum vitae of Dr. Lichten.

MARK W. RUF (#0047100)
Hoyt **Block**, Suite 300
700 W. St. Clair Ave.
Cleveland, Ohio 44113
(216) 687-1999

ROBERT F. LINTON, JR. (#0017504)
Linton & Hirshman
Hoyt **Block**, Suite 300
700 W. St. Clair Ave.
Cleveland, Ohio 44113
(216) 771-5800

Attorneys for Plaintiffs

CERTIFICATE OF SERVICE

The foregoing Sixth Request for Production of Documents has been served via fax U.S. mail this ____ day of October, 2001 upon the following:

James L. Malone, Esq.
Reminger & Reminger
113 St. Clair Avenue, NE
Cleveland, Ohio 44114-1841

MARK W. RUF (#0047100)

S:\MWR\Zimmerman\Pleadings\Discovery\RPD.7.wpd

IN THE COURT OF COMMON PLEAS
CUYAHOGA COUNTY, OHIO

MARY LOU ZIMMERMAN, et al,

Plaintiffs

-VS-

CLEVELAND CLINIC FOUNDATION,

Defendant

CASE NO. 399411

JUDGE JANET R. BURNSIDE

**RESPONSES BY DEFENDANT TO
PLAINTIFFS' SIXTH REQUEST
FOR PRODUCTION OF DOCUMENTS**

REQUEST NO. 1: All policies, procedures and protocols relating to the IRB and experimental surgical procedures performed at The Cleveland Clinic in effect in 1998.

RESPONSE: Objection. The request for production refers to "experimental" surgical procedures. That term is vague, ambiguous and without an ascertainable meaning as it relates to the Institutional Review Board and the subject matter of this lawsuit. An Institutional Review Board is established to review certain research involving human subjects.

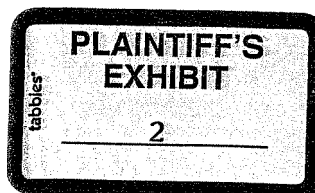
Without waiving the objection, the IRB in 1998 operated pursuant to policies and procedures set forth in 45 CFR 46 and The Belmont Report.

Objection. The request for production of documents utilizes the ambiguous term, "protocols." The activities of the Institutional Review Board are governed by policies and procedures, which policies and procedures are being provided as set forth above. If this request is intended to encompass research protocols, it is overbroad, burdensome, harassing, oppressive, and not reasonably calculated to lead to the discovery of admissible evidence.

REQUEST NO. 2: All policies, procedures and protocols relating to the IRB and experimental surgical procedures performed at The Cleveland Clinic in effect in 2000-2001. This shall include, but not be limited to those relating to Dr. Rezai's current research project with Belgium, Brown University, and The Cleveland Clinic relating to neurosurgical treatment of OGD, as testified to at p. 33-35 of his deposition, attached as Exhibit A.

RESPONSE: Objection. The request for production refers to "experimental" surgical procedures. That term is vague, ambiguous and without an ascertainable meaning as it relates to the Institutional Review Board and the subject matter of this lawsuit. An Institutional Review Board is established to review certain research involving human subjects.

Objection. The Institutional Review Board policies and procedures are proprietary and confidential.



Without waiving the previous objection, a copy of The Cleveland Clinic Foundation's Institutional Review Board policies and procedures will be available for inspection at the deposition of the IRB Chair, Dr. Alan Lichtin, on December 5, 2001 at 9:00 a.m. Disclosure or duplication of the contents of The Cleveland Clinic Foundation Institutional Review Board policies and procedures shall not be made to any individual or entity, except as provided pursuant to a Stipulated Protective Order.

Objection. The request for production of documents utilizes the ambiguous term, "protocols." The activities of the Institutional Review Board are governed by policies and procedures, which policies and procedures are being provided as set forth above. If this request is intended to encompass research protocols, it is overbroad, burdensome, harassing, oppressive, and not reasonably calculated to lead to the discovery of admissible evidence.

With respect to Dr. Rezai's research project, see Response to Request for Production No. 5.

REQUEST NO. 3: Documents identifying all members of the IRB in 1998.

RESPONSE: Attached.

REQUEST NO. 4: Documents identifying all members of the IRB in 2000-2001.

RESPONSE: Attached.

REQUEST NO. 5: All documents relating to the IRB review of any psycho surgical procedures performed or considered at The Cleveland Clinic. This shall include, but not be limited to, lobotomy: cingulotomy, capsulotomy, combined cingulotomy and capsulotomy, and deep brain stimulation.

RESPONSE: Attached.

REQUEST NO. 6: A current curriculum vitae of Dr. Lichtin.

RESPONSE: Attached.



James L. Malone (0019178)
Marilena DiSilvio (0064575)
Alan B. Parker (0040008)
REMINER & REMINGER CO., L.P.A.
The 113 St. Clair Building, N.E. - Suite 700
Cleveland, Ohio 44114
Phone: (216) 687-1311
Fax: (216) 687-1841
e-mail: jmalone@reminger.com
mdisilvio@reminger.com
aparker@reminger.com

Attorneys for Defendant,
The Cleveland Clinic Foundation

CERTIFICATE OF SERVICE

The foregoing Response to Plaintiffs' Sixth Request for Documents was forwarded to counsel this 4th day of December, 2001, as follows:

Robert F. Linton, Jr.
Mark W. Ruf
700 W. St. Clair Avenue
Cleveland, Ohio 44113

Attorneys for Plaintiffs



JAMES L. MALONE (0019178)
MARILENA DISILVIO (0064575)
ALAN B. PARKER (0040008)

ABP/dn

**MULTIPLE PROJECT ASSURANCE OF COMPLIANCE WITH DHHS REGULATIONS
FOR PROTECTION OF HUMAN RESEARCH SUBJECTS**

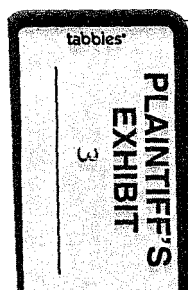
IRB Name: Institutional Review Board of the Cleveland Clinic Foundation, 9500 Euclid Avenue, Wb2, Cleveland, Ohio 44195 / (216) 444-2924
IRB Identification Number: M-1388

Member Name	Highest Degree Earned	Scientific Specialty	Affiliation with Institution
Alan Lichtin (Chair)	M.D.	Hematology/Medical Oncology	Employee
Michael Lauer (Vice Chair)	M.D.	Cardiology	Employee
Martin Smith (2nd Vice Chair)	S.T.D.	None (Bioethics)	Employee
Nita Marie Bedocs	M.S.N., R.N.	Nursing	Employee
Douglas Chyalle	M.D.	Cerebrovascular Surgery	Employee
Diane Hughes Dobrea	M.S., J.D.	None (Law)	Employee
Sheila D. Howard	C.C.R.A.	None (IRB Manager)	Employee
George Kanoli	S.T.D.	None (Bioethics)	Employee
Paul Lauritzen	Ph.D.	None	None
Richard Naugle	M.D.	Psychiatry	Employee
Pamela Mason	Ph.D.	None	None
Michael J. Meehan	J.D.	None (Law)	Employee
Linda Lewicki	Ph.D., R.N.	Nursing Research	Employee
Gregory Plautz	M.D.	Surgical Research Center	Employee
Jeffrey Ross	M.D.	Neuroradiology	Employee
Kenneth Shermock	Pharm.D.	Pharmaco Economics	Employee
Rita M. Steffen	M.D.	Pediatric/Gastroenterology	Employee
Alternates			
Johanna Goldfarb	M.S.	Pediatric Surgery/Infectious Disease	Employee
Consultants			
Angelo A. Licata	M.D., Ph.D.	Endocrinology	Employee
Xiaowei (Winnie) Zhu	M.S.	Radiation Safety	Employee
Donald Neumann	M.D., Ph.D.	Nuclear Medicine	Employee
Michael Kutner	Ph.D.	Biostatistics	Employee
Michael Southworth	RAC, CGQ, CGQ	Quality Assurance & Regulatory Affairs	Employee

OFFICE OF THE INSTITUTIONAL REVIEW BOARD

Sheila D. Howard, CCRA, IRB Manager

rev. 12123198 Appendix C



**MULTIPLE PROJECT ASSURANCE OF COMPLIANCE WITH DHHS REGULATIONS
FOR PROTECTIONS OF HUMAN RESEARCH SUBJECTS**

IRB Name: Institutional Review Board of the Cleveland Clinic Foundation, 9500 Euclid Avenue, Wb2, Cleveland, Ohio 44195 (216-444-2924)

IRB Identification Number: M-1388

PRIMARY MEMBER NAME AND ALTERNATE (ALTERNATE IS SHADOWED)	HIGHEST DEGREE EARNED	SCIENTIFIC SPECIALTY	AFFILIATION WITH INSTITUTION	SCIENTIFIC/NON-SCIENTIFIC
Alan Lichtin (Chair)	MD	Hematology and Medical Oncology	Employee	Scientific
Alternate - Jay Ciozki	MD	Radiation Oncology	Employee	Scientific
Michael Lauer (Vice Chair)	MD	Cardiology	Employee	Scientific
Alternate - Sasan Ghaffari	MD	Cardiology	Employee	Scientific
Martin Smith (2nd Vice Chair)	STD	S.T.D. Bioethics	Employee	Non-Scientific
Linda Lewicki (3rd Vice Chair)	PhD, RN	Nursing Education & Research	Employee	Scientific
Alternate - Michelle Dumpe	PhD, RN	Nursing Education & Research	Employee	Scientific
Nita Marie Dedoes	MSN, RN	Rheumatic and Immunologic Disease	Employee	Scientific
Alternate - Monica Weber	RN	Advanced Practice Nursing	Employee	Scientific
Darwin Conwell	MD	Gastroenterology	Employee	Scientific
Alternate - John Dumot	DO	Gastroenterology	Employee	Scientific
Thomas Hunt	MD	Orthopaedic Surgery	Employee	Scientific
Alternate - Brian Donley	MD	Orthopaedic Surgery	Employee	Scientific
Paul Lauritzen	PhD	Religious Studies	Community Representative	Non-Scientific
Alternate - Andrew Trew	PhD	Philosophy	Community Representative	Non-Scientific
Richard Naugle	PhD	Neuropsychology	Employee	Scientific
Alternate - Lisa Stanford	PhD	Neuropsychology	Employee	Scientific
Pamela Mason	PhD	Political Science	Community Representative	Non-Scientific
Alternate - Brenda Wickes	PhD	Philosophy/Ethics	Community Representative	Non-Scientific
Michael J. Meehan	JD	General Counsel	Employee	Non-Scientific
Jeffrey Ross	MD	Radiology	Employee	Scientific
Kenneth Shernock	PharmD	Hospital Pharmacy	Employee	Scientific
Alternate - Donald Carroll	R.Ph	Home Care Pharmacy	Employee	Scientific
Michael Southworth	RAC, CQE, CQA	Biomedical Engineering	Employee	Scientific
Rita M. Steffen	MD	Pediatric Gastroenterology	Employee	Scientific
David Weng	MD	Hematology/Oncology	Employee	Scientific

tabbies

PLAINTIFF'S
EXHIBIT
4

**MULTIPLE PROJECT ASSURANCE OF COMPLIANCE WITH DHHS REGULATIONS
FOR PROTECTIONS OF HUMAN RESEARCH SUBJECTS**

IRB Name: Institutional Review Board of the Cleveland Clinic Foundation, 9500 Euclid Avenue, Wb2, Cleveland, Ohio 44195 (216-444-2924)

IRB Identification Number: M-1388

(CONTINUED) PAGE 2

CONSULTANT NAME	HIGHEST DEGREE EARNED	SCIENTIFIC SPECIALTY	AFFILIATION WITH INSTITUTION	SCIENTIFIC/NON-SCIENTIFIC
Angelo A. Uccala	MD, PhD	Endocrinology	Employee	Scientific
Stuart Kline	CIH, CSP, CSM, CHMM	Environmental Health and Safety	Employee	Scientific
Donald Neumann	MD, PhD	Nuclear Medicine	Employee	Scientific
Jennifer Gassman	PhD	Biostatistics and Epidemiology	Employee	Scientific
Jonathan Waters	MD	General Anesthesia	Employee	Scientific
Jean Pierre Yard	MD	Cardiothoracic Anesthesia	Employee	Scientific
Ronald Bukowski	MD	Hematology and Medical Oncology	Employee	Scientific

OFFICE OF THE INSTITUTIONAL REVIEW BOARD: Paul Papagni, JD, Executive Director
 Michela Adams, CPHQ, CIM, Administrative Program Coordinator
 Deborah McCleave, IRB Office Manager

Effective 06/07/00 (Appendix C)

MULTIPLE PROJECT ASSURANCE OF COMPLIANCE WITH DHHS REGULATIONS
FOR PROTECTIONS OF HUMAN RESEARCH SUBJECTS

IRB Name: Institutional Review Board of the Cleveland Clinic Foundation, 9500 Euclid Avenue, Wb2, Cleveland, Ohio 44195 (216-444-2924)
IRB Identification Number: M-1388 Expiration: 8/31/2003
Version: 9/12/01

PRIMARY MEMBER NAME AND ALTERNATE (ALTERNATE IS SHADED)	HIGHEST DEGREE EARNED	SCIENTIFIC SPECIALTY	AFFILIATION WITH INSTITUTION	SCIENTIFIC/NON-SCIENTIFIC
Alan Lichlin (Chair)	MD	Hematology/Oncology	Employee	Scientific
Alternate - Joseph Frolik	MD, PhD	Preventive Medicine	Employee	Scientific
Michael Lauer (Vice Chair)	MD	Cardiology	Employee	Scientific
Alternate - Susan Giallari	MD	Cardiology	Employee	Scientific
Linda Lewicki (2nd Vice Chair)	PhD, RN	Nursing Education & Research	Employee	Scientific
Alternate - Lorraine Miron	PhD, RN	Nursing Education & Research	Employee	Scientific
Nita Marie Dedocs	MSH, RN	Clinical Res Specialist-LOA	Employee	Scientific
Alternate - Monica Weber	RN	Infectious Disease	Employee	Scientific
Richard Naugle	PhD	Neuropsychology	Employee	Scientific
Alternate - Kathleen Franco	MD	Psychiatry and Psychology	Employee	Scientific
Andrew Trew	PhD	Community Representative	None	Non-Scientific
Alternate #1 - Paul Lantzen	PhD	Community Representative	None	Non-Scientific
Alternate #2 - Brenda Winkus	PhD	Community Representative	None	Non-Scientific
Alternate #3 - Pam Mason	PhD	Community Representative	None	Non-Scientific
Michael J. Moohan	JD	General Counsel	Employee	Non-Scientific
Alternate - Jan Serkey	JD, RN	General Counsel	Employee	Scientific
Jeffrey Ross	MD	Radiology	Employee	Scientific
Alternate - Jay Clotzki	MD	Radiation Oncology	Employee	Scientific
Kenneth Shermock	PharmD	Hospital Pharmacy	Employee	Scientific
Alternate - Donald Carroll	R.Ph.	Home Care Pharmacy	Employee	Scientific
Stephen Davis	MD	Pediatric	Employee	Scientific
Alternate - Rita M. Steffen	MD	Pediatrics Gastroenterology	Employee	Scientific
David Wang	MD	Hematology/Oncology	Employee	Scientific
Alternate - Gordon Sikalovic	MD, PhD	Hematology/Oncology	Employee	Scientific
PAUL FORD	PhD	BIOETHICS	Employee	Non-Scientific
ALTERNATE - SUSAN BILLYUE	RN	OB/GYN	Employee	Non-Scientific
WAYNE DAUM	MD	ORTHOPAEDICS	Employee	Scientific
DANIEL BEYER (NON-VOTING)	MS, MHA	IRB EXECUTIVE DIRECTOR	Employee	Non-Scientific

STUDY INFORMATION

Study #: IRB 4498

Prior numbers:

Study title: Electrical Stimulation of the Internal Capsule for Intractable
Obsessive-Compulsive Disorder

Principal inv: Rezai, Ali R.

Co-inv 1: Dackiewicz, Doreen

Co-inv 2: Malone, Donald A.

Co-inv 3: Montgomery, Erwin B.

Co-inv 4: Chelune, Gordon Ph.D

Sponsor info: Internal

Through version: Protocol/description; Conditional Letter from FDA dated 7/13/01

Eligible for expedited rev? No

Status: ACTIVE

Vulnerable subjects:

Informed Cons.; Written informed consent required

PI DEPT..... Neurosurgery

Conflict of interest:

Drugs & devices: No

Date closed or next review: August 2, 2002

Date closed to accrual:

Date first approved: October 5, 2001

Date last Action: October 5, 2001

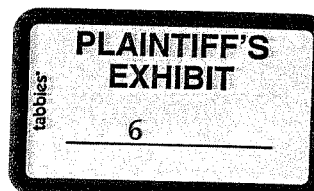
Date purged:

Date suspended:

Date terminated:

Deadline suspension:

Deadline termination:



STUDY INFORMATION

Study #: IRB 3431

Prior numbers:

Study title: The Effects of Subthalamic Nucleus Deep Brain Stimulation on Sleep in Patients with Parkinsons Disease

Principal Inv: Foldvary, Nancy

Co-inv 1: Wang, George

Co-inv 2: Dinner, Dudley S

Co-inv 3: Montgomery, Erwin B.

Co-inv 4:

Sponsor info: Internal

Through version: the letter from the FDA dated 08/30/01 regarding two cases of

Eligible for expedited rev? *Yes*

Status: ACTIVE

Vulnerable subjects: none

Informed Cons.: Written informed consent required

PI DEPT..... Epilepsy/Sleep Research

24

Conflict of inreresi:

Drugs & devices: No

Date closed or next review: December 2, 2001

Date closed to accrual:

Date first approved: November 5, 1999

Date last Action: November 1, 2031

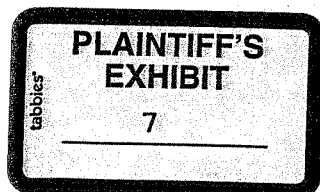
Date purged:

Date suspended:

Date terminated:

Deadline suspension:

Deadline termination:



To: Dr. Lichten

TO: Stagno, Susan, P57

FROM: Office of *the* Institutional Review Board, WbZ

RE: RPC 3032 "Cingulotomy in the treatment of intractable
obsessive-compulsive disorder(OCD)"

Project Period: 8/16/89 to 8/12/94

IRB file on this study is no longer available.



CURRICULUM VITAE

Alan Eli Lichtin, M.D.

Home Address: 6295 Fairhaven Road
Mayfield Heights, OH 44124

Office Address: The Cleveland Clinic Foundation
9500 Euclid Avenue, Desk R35
Cleveland, OH 44195-5123

Social Security Number: 272-50-8486

Date of Birth: November 12, 1955

Place of Birth: Cincinnati, Ohio

Marital Status: Married 1983 - Joni

Children: 1986 - Jared
1988 - Chad

Education: 1973-1976 B.S. University of Cincinnati
1976-1980 M.D. University of Cincinnati

Postgraduate Training and Fellowship Appointments:

1980-81	Intern in Medicine, Case-Western Reserve University Hospitals, Cleveland, Ohio
1981-83	Resident in Medicine, Case-Western Reserve University Hospitals, Cleveland, Ohio
1983-86	Fellow in Hematology-Oncology, Hospital of the University of Pennsylvania, Philadelphia, PA

Academic Appointments: 1986-88 Assistant Professor, Internal Medicine, Section of Hematology/Oncology, University of Missouri, Kansas City, MO



Academic Appointments
(continued):

- 1988-present Staff Physician, Dept. of
Hematology/Medical Oncology,
Cleveland Clinic Foundation,
Cleveland, OH
- 1993-present Clinical Assistant Professor,
Department of Internal Medicine,
Ohio State University

Specialty Certification:

- 1983 Diplomate of the American
Board of Internal Medicine
- 1985 Diplomate of the American
Board of Internal Medicine
in Medical Oncology
- 1986 Diplomate of the American
Board of Internal Medicine
in Hematology

Licensure:

Ohio #48291

Awards Honors and Memberships in Honorary Societies:

- 1976 Phi Beta Kappa
- 1979 Alpha Omega Alpha
- 1980 David Confer Award for Excellence in Pathology
- 1985 McCabe Foundation Award, to pursue research
on the effect of retinoids on melanoma
- 1987 Lettie B. McIlvain Frederic Fund grants for
research of 1) Protein C levels in Sickle cell
anemia and 2) Measurement of Platelet
Associated IgG in Pre-eclampsia.
- 1987 Councilor Alpha Omega Alpha, Delta Chapter of
Missouri, UMKC, School of Medicine
- 1987 Faculty Research Grant, University of Missouri
System
- 1992- Appointed Hematology representative,
1996 Physicians Advisory Committee, State of
Ohio Medicare Carrier.
- 1993 Appointed Board of Trustees, Northern
Ohio Chapter, Leukemia Society of America
- 1993 Maimonides Award, Physicians Division, Jewish
Community Federation of Cleveland.
- 1993 Awarded Bruce Hubbard Stewart Fellowship
- 1998 Philosophi Award, Phi Beta Kappa

Professional Affiliations:

American Society of Clinical Oncology
American Society of Hematology
American Association for the Advancement of
Science
international Society of Experimental
Hematology
international Society on Thrombosis and
Hemostasis
European Hematology Association
American Medical Association
Applied Research Ethics National Association
(ARENA)

Principal Investigator:

1. CCF PI for cooperative grant with Leslie Schover Ph.D.. Interactive media on banking sperm before cancer therapy.
2. PI - IDEC study: A Phase II, Randomized Open Label, Multiple Dose Finding, Safety and Clinical Activity study of IDEC - 131 (monoclonal antibody against CD154) in patients with chronic refractory IT?.

Committee Assignments:

1989-1997	Institutional Review Board Adult and Pediatric, First Vice-Chair
1997-present	Promoted to Chairman
1990-1997	Chairman (1992) Medical Records and Statistics Committee, Cleveland Clinic Foundation
1992-present	Committee on Practice, American Society of Hematology
1994-present	Cancer Committee, CCF
1995-1997	Elected, Medical Division Committee, CCF
1995-1996	Chairman, Ad Hoc Committee on Practice Guidelines, American Society of Hematology
1997-present	Member, American Society of Hematology, Committee for the Optimization of Hematologic Care

Committee Assignments

(continued):

1999-present Reelectd, Medical Division Committee
CCF

1999-present Co-chair, Erythropoietin Guideline
writing committee, ASH & ASCO

Abstracts:

1. Lichtin **AE**, and Silberstein **LE**. Plasma and whole blood exchange in thrombotic thrombocytopenic purpura. Proceedings of the American Society of Hematology, Blood, 66(5) supplement, 292a.
2. Lichtin AE, TerKonda R, Shannon R, and Sirridge M. Protein C levels in sickle cell anemia. Proceedings of American Society of Hematology, Blood, 70(5), supplement 1, 116.
3. Harden E, Bolwell B, Faye J, Wolff S, Phillips G, Stevens D, Lichtin AE, Reece D, Brown R, and Herzig R: Treatment of progressive Hodgkin's disease with Cyclophosphamide, BCNU and continuous infusion etoposide: CBVi and Autologous Marrow Transplantation: Proceedings of the American Society for Clinical Oncology, 1990, Washington, D.C.
4. Lichtin AE, Weick J, Andresen S, Burwell R, Sands K, Murar A, Bauer L, Fishleder A, Green R, and Bolwell B. Treatment of metastatic breast cancer with high dose chemotherapy followed by autologous bone marrow transplantation. Proceedings of American Society of Clinical Oncology, 1991.
5. Kalaycio M, Lichtin **AE**, Andresen S, Burwell R, Murar A, Yanssens T, and Bolwell B. The Busulfan and Cyclophosphamide (BuCy2) pre-parative regimen followed by autologous progenitor cell rescue (ABMT) is safe and effective for patients with breast cancer. Proceedings of American Society of Clinical Oncology, 1993.
6. Nicely C, Edinger M, McNealis M, Cwen M, Stoler M, Hussein M, Lichtin **AE**, Finke J, and Tubbs R: Down regulation of multiple lymphocyte adhesion molecule and homing receptor expression across all grades of 6-cell non-Hodgkin's Lymphomas. Abstract. International Association of Pathology, March 1993.
7. Bolwell B, Fishleder A, Bauccho P, Lichtin **AE**, Andresen S, Burwell R, Yanssens T, Koc A, and Green R: Peripheral Blood progenitor cell harvesting using G-CSF priming: Factors influencing cell yield. Abstract, Proceedings of the American Society of Hematology, December 1992.
8. Bolwell B, Fishleder A, Bauccho P, Yanssens T, Burwell R, Lichtin **AE**, Andresen S, Koc A, and Green K: G-CSF primed peripheral blood progenitor cells enhances neutrophil and platelet engraftment in autologous bone marrow transplantation. Abstract, Proceedings of the American Society of Hematology, December 1992.

Abstracts (continued):

9. Kalaycioglu M, Lichtin AE, Andresen S, Fishleder A, Tuason L, Copeland E, and Bolwell B. Major ABO incompatible allogeneic Bone Marrow Transplantation after treatment with Busulfan and Cyclophosphamide. Proceedings of International Society of Experimental Hematology, Rotterdam, 1993.
10. Boiweli B, Dannley R, Goormastic M, Yanssens T, Baucoco P, Andresen S, **Lichtin AE**, and Fishleder A. Comparison of G-CSF with GM-CSF for mobilization of peripheral blood progenitor cells and for enhancement of marrow post autologous bone marrow transplant. Blood, 82(10), suppl. 1, 83a.
11. Pohlman B, Goormastic M, Dannley RA, **Lichtin AE**, Andresen SA, and Bolwell B. Primed peripheral blood progenitor cells with or without bone marrow for hematopoietic reconstitution. Blood, 82(10), suppl. 1, 289a.
12. Wos E, Hoeltge G, Tucson L, and Lichtin AE. Clinical and laboratory analysis of patients with deletions of part of chromosome 5q⁻. Blood, 82(10), suppl. 1, 535a.
13. Overmoyer B, Dannley R, Goormastic M, Andresen S, Lichtin AE, and Bolwell B. Consolidation for high risk breast cancer with high dose chemotherapy and autologous bone marrow rescue. Proceedings of American Society of Clinical Oncology, Dallas, 1994.
14. Bolwell B, Kalaycioglu M, Pohlman B, Baucoco P, Lichtin AE, Andresen S, Goormastic M, Dannley R, Vukovich K, and Fishleder A. T-cell depletion (TCD) of CD8⁺ cells is associated with an increased risk of graft failure but not relapse in CML using busulfan based preparative regimens. Blood, 84(10), suppl. 1, 1344.
15. Smith H, Mendez **Z**, Moir R, Hoeltge G, and Lichtin **AE**. Negative prognostic impact of additional chromosomal abnormalities with monosomy 7. Blood, 84(10), suppl. 1, 2530.
16. Pohlman B, Dannley R, Kalaycioglu M, Lichtin **AE**, Andresen A, and Bolwell B. Growth factor mobilized peripheral blood progenitor cells are sufficient to sustain long term hematopoiesis following myeloablative chemotherapy. Blood, 84(10), suppl. 1, 2856.
17. Bolwell B, Dannley R, Zgrabick J, Lichtin AE, Andresen S, Pohlman B, Tate J, *Goormastic M*, Sands K, and Kalaycioglu M. Analysis of factors influencing the yield of bone marrow harvest in the out-patient setting. Blood, 84(10), suppl. 1, 2917.
18. Bolwell B, Andresen S, Lichtin AE, Overmoyer B, Pohlman B, Goormastic M, Dannley R, Mendez **Z**, and Wakeling A. ABMT for large cell lymphoma: Mature follow-up of the CBV preparative regimen. Blood, 86(10), suppl. 1, 938a, 1995.
19. Tandon R, Tuason L, Hoeltge G, and Lichtin **AE**. Clinical characteristics of patients with 20q⁻ chromosome deletion. Blood, 86(10), suppl. 1, 333a, 1995.

Abstracts (continued):

20. Sharma S, Zuccaro K, Kalaycioglu M, Andresen A, Lichtin **AE**, Pohlman B, Long T, and Hussein MA. Pre-medication for platelet transfusion - A prospective study on the efficacy of four commonly used regimens. *Blood*, 86(10), suppl. 1, 354a, 1995.
21. Fischer T, Miller M, and Lichtin **AE**. Unusual forms of post-transplant lymphoproliferative disorder after cardiac transplantation: plasmacytoma and large cell lymphoma with plasma cell hyperplasia. *Blood*, 86(10), suppl. 1, 812a, 1995.
22. Beckmann MJ, Hussein MA, Lichtin **AE**, Jacobsen DW, Manteuffel L, and Green R. Low serum vitamin B₁₂ in patients with plasma cell myeloma is associated with true functional cobalamin deficiency. Abstract presentation to the American Society of Clinical Pathology, 1995 meeting.
23. Boiwell BJ, Wakeling A, Dannley R, Goormastic M, Andresen S, Lichtin **AE**, Overmoyer B, Pohlman B, and Kalaycio M. Late relapse after ABMT for Hodgkin's Disease. *Blood*, 88(10), p 122a, 1996.
24. Andrich S, Hoeltge G, Tuason L, and Lichtin **AE**. Clinical characteristics of patients with 11q23 chromosome abnormality. *Blood*, 88(10), 151b, 1996.
25. George R, Hoeltge G, Tuason L, and Lichtin **AE**. Clinical characteristics of patients with trisomy 8. *Blood*, 88(10), 155b, 1996.
26. George C, Tripp B, Hussein M, Lichtin **AE**, Andresen S, Overmoyer B, Pohlman B, and Kalaycio M. Effective treatment for poor risk acute myelogenous leukemia (AML): A potential role for timed sequential therapy with concomitant G-CSF. *Blood*, 88(10), 173b, 1996.
27. Tubbs R, Nicely C, Finke J, Bukowski R, and Lichtin **AE**. Heterogeneous expression of multiple adhesion molecules by B-cell non-Hodgkin's lymphoma. *Blood*, 88(10), 189b, 1996.
28. Bolwell B, Wise K, Pohlman B, Andresen S, Koo A, Goormastic M, Overmoyer B, Lichtin **AE**, Miller M and Kalaycio M. CD34⁺ cell collection is a dynamic process. Proceeding American Society Hematology Annual Meeting, 1998.
29. Bolwell B, Pohlman B, Overmoyer B, Andresen S, Goormastic M, Dannley R, Serafin M, Lichtin **AE**, Wise K and Kalaycio M. The G-CSF primed WBC correlates with CD34⁺ cell yield. ASH, 1998.
30. Molto L, Bloom T, Ravman P, Tubbs R, Hsi E, Bukowski R, Lichtin **AE**, Olencki T and Finke J. Impaired T cell stimulatory capacity of tumor-stroma NHL B cells. AACR Annual Meeting, April, 1999.
31. Bolwell B, Pohlman B, Kalaycio M, Goormastic M, Andresen S, Lichtin **AE**, and DeMars D. Long-term follow-up of autologous transplantation for non-Hodgkin's lymphoma. ASCO, 1999.

Abstracts (continued):

32. Srkalovic G, George R, Sen K, Thamilarasan M, Klein A, and Lichtin AE. Doppler echocardiographic assessment of diastolic cardiac function in patients with transfusional iron overload. Blood, 1999 94(10), suppl. 21 b.
33. Bolwell B, Kalaycio M, Lichtin AE, Anresen S, Fishleder A, Goormastic M, McBee M, Sands K, Serafino S, Sobecks R, Eles M, Johnston G, and Poniman B. CD34+ cell yield of bone marrow harvested from normal donors progressively declines with harvested marrow. Blood, 96 (11), suppl. 1, 180a, 2000.
34. Bussel J, Aledort L, Hayward C PM, Kelton J, Lichtin AE, McMillan R, Nierodzik M L, George J, Wasser J, Zumberg M, Saba H, Towell B, Gayko U, Cruickshank S, and Nichol J L. A prospective cross-sectional study to characterize selected autoimmune (AI) markers and report the incidence of antithrombopoietin antibodies (α TPO) in patients with immune thrombocytopenic purpura (ITP). Blood, 96 (1), suppl. 1, 250a, 2000.

Presentations:

1. Lichtin AE, Guerry D, Elder DE, Hamilton R, LaRossa D, Herlyn D, Iliopoulos D, Thurin J, Steplewski Z. A Phase I study of monoclonal antibody therapy in disseminated melanoma. Proceedings of the XIII International Pigment Cell Conference, 1986. Poster.
2. Guest Lecturer, Mary Ann Thompson Memorial Cancer Seminar, sponsored by Johnson County Community College, The Environment and Cancer, June 10, 1987.
3. TerKonda R, Ebbinghaus S, Shannon R, Sirridge M, Lichtin AE. Protein C in sickle cell anemia, New York Academy of Sciences, Sickle Cell Diseases - Current Perspectives, April 11, 1988, poster.
4. Ebbinghaus S, Shannon R, Sirridge M, Maulik D, Lichtin AE. Platelet associated IgG in pre-eclampsia. Southern Medical Association National Meeting, November, 1988
5. Lichtin AE, Iliopoulos D, Guerry D, Elder D, Herlyn D, Steplewski Z. Therapy of melanoma with an anti-melanoma ganglioside monoclonal antibody: A possible mechanism of a complete response. American Society of Clinical Oncology, New Orleans, May 1988, poster.
6. Guest Lecture: "Missouri Hemophilia Treatment Program - The AZT Study". AIDS - A Public Health Response, sponsored by Missouri Department of Health, St. Louis, MO, March 1988.
7. Lichtin AE. Late Effects of Cancer Therapy. Oncology Nursing Symposium, Cleveland Clinic Foundation, Cleveland, OH, October 17, 1989.
8. Grand Rounds, Cleveland Clinic Foundation, Cyclosporine - Use in hematologic diseases, Cleveland, OH, October 26, 1989.

Presentations Continued:

9. Grand Rounds, St. Alexis Hospital, Cleveland, OH. Coagulation Disorders, November 18, 1989.
10. Bolwell B, Fishieder A, **Lichtin AE**, Koo A, Camisa C, Green R, Barna B. Photopheresis in the treatment of chronic graft -vs- host disease. Proceedings of the American Society of Hematology, Blood, 76, supplement 1, 529a, 1990, poster.
11. Bolwell B, Lichtin **AE**, Andresen S, Weick J, Burwell R, Sands K, Murar A. Treatment of relapsed intermediate or high grade non-Hodgkin's lymphoma with high dose cyclophosphamide, BCNU, and etoposide and autologous bone marrow transplantation. Proceedings of the American Society of Hematology, Blood, 76, supplement 1, 529a, 1990, poster.
12. Lecturer, CCF Health Awareness Series, Cancer Treatment for the 90's, April 25, 1990.
13. Guest lecturer, Cancer and Minorities, Cleveland Health Education Museum, May 1, 1990.
14. Lecturer, Intensive Review of Internal Medicine, Disorders of Erythrocytes, June, 1990, June 1991 and June 1992.
15. Lecturer, Cuyahoga Community College Surgeon's Assistant Program, Anemia, Bleeding Disorders, Leukemias and Immunologic Disorders, July 18, 1990.
16. CME Program, Barberton Citizen's Hospital, Bone Marrow Transplantation, Barberton, OH, September 27, 1990.
17. Grand Rounds, Cleveland Clinic Foundation, Inhibitors of Coagulation, January 16, 1991.
18. Men's Cancer Detection and Prevention, BP America Health Lecture Series, January 29 and January 30, 1991.
19. Continuing Medical Education conference, Anemia-Recognition and Management, St. Joseph's Riverside Hospital, Warren, OH, February 9, 1991.
20. Shields RW, Estes M, Roaers LR, **Lichtin AE**, Mitsumoto H: Sensory Polyneuritis with Peripheral Lymphocytosis- Proceedings of American Association of Neurology, 1991.
21. Bolwell B, **Lichtin AE**, Andresen S, Burwell R, Sands K, Koo A, Owen N, Baucoco P, Fishleder A: G-CSF and Peripheral Primed Progenitor cells (PPPC) Enhances Engraftment In Autologous Bone Marrow Transplantation (ABMT) For Non-Hodgkin's Lymphoma (NHL) And Hodgkin's Disease (HD). Proceedings of American Society of Hematology, 78 (10), supplement 1, p. 242a, 1991, poster.
22. Guest Lecturer, International Symposium on Biotherapy of Cancer, Growth Factors in ABMT and Future Applications of IL-3, Pamplona, Spain, October 11, 12, 1991.

Presentations Continued:

23. Bolwell B, Lichtin AE, Andresen S, Burwell R, Sands K, Koo A, Owen N, Baucoco P, Fishieder A. G-CSF and peripheral primed progenitor cells (PPPC) enhances engraftment in autologous bone marrow transplantation for non-Hodgkin's lymphoma and Hodgkin's Disease, Proceedings of the American Society of Hematology, Denver, Colorado, 1991.
24. Bolwell B, Lichtin AE, Murar A, Burwell R: An Analysis of Outpatient Bone Marrow Harvesting Proceedings of Bone Marrow Transplantation Symposium, UCLA. Keystone, CO, 1992. Poster.
25. Guest Lecturer, Amyloidosis. Medical Grand Rounds, Beaver Medical Center, Beaver, PA. February 7, 1992.
26. Grand Rounds, "Update of Management of Disseminated Intravascular Coagulation." St. Joseph Riverside Hospital, Warren, Ohio, November 14, 1992.
27. Guest Lecturer, "Platelets and New Topics in Hemostasis", Helena Laboratories sponsored symposium, October 1, 1992.
28. Grand Rounds, "Non-Hodgkin's Lymphoma - An Update", Fairview General Hospital, November 23, 1992.
29. Grand Rounds, Leukemia in the Elderly, St. Alexis Hospital, February 19, 1993.
30. Guest Lecturer, Update, DIC, Lutheran Medical Center, February 24, 1993.
31. CCF Medical Grand Rounds, "Bleeding and Clotting, What's Common and What's Not?" with Drs. Jerry Bartholomew and Kandice Kotke-Marchant, April 22, 1993.
32. Guest Lecturer, "The Role of Nuclear Medicine in Hematology-Oncology." Central Chapter of the Society of Nuclear Medicine. April 24, 1993.
33. Guest Faculty, Medical Institute for Law, "Issues in the Creation and Management of the Medical Record." Cleveland-Marshall College of Law. June 3, 1993.
34. Lecturer, Internal Medicine Board Review Course, "Red Cell Disorders," June, 1993.
35. Guest Speaker, "Anticardiolipin Antibodies." Helena Labs Symposium, New York City, July, 1993.
36. Guest, Radio Show, "Leukemia". Fostoria. OH. September 3, 1993.
37. Lecturer, "Nutritional Anemias." CCF Nutrition Seminar Series, October 15, 1993.
38. Lecturer, "Common Hematologic Problems in Cancer Patients." CCF Palliative Care Grand Rounds, January 20, 1994.

Presentations Continued:

39. Lecturer, "Leukemia." Cleveland Health Careers Magnet High School. February 7, 1994.
40. Guest Lecturer, "Promising Treatment of Chronic Leukemia", annual meeting of the Board of Trustees of Northern Ohio Chapter of Leukemia Society of America, April 1994.
41. Guest Lecturer, Tumor Board, St. Johns West Shore Hospital, "Non-Hodgkin's Lymphoma", April 12, 1994.
42. Lecturer, CCF Internal Medicine Review Course, "Red Cell Disorders", June 16, 1994.
43. Lecturer, Fifth Annual Medical Institute for Law Faculty, CCF/Cleveland Marshall College of Law, June 1994.
44. Lecturer, "Platelets & Clotting". Lutheran Medical Center Internal Medicine Conference, November 8, 1994.
45. Lecturer, CCF Surgery Residents, Clotting Disorders, November 21, 1994.
46. Poster presentation, American Society of Hematology, 1995 meeting: Tandon R, Tuason L, Hoeltge G, **Lichtin AE**. Clinical characteristics of patients with 20q- chromosome deletions.
47. Lecturer, Amgen Preceptorship, CCF Experimental Therapeutics Program, March 1, 1996.
48. Lecturer, "Practice Guidelines in Hematology", CCF Experimental Therapeutics ASH Review, January 15, 1997.
49. **Lichtin AE**, Anderson K, Bloomer J, Bolwell B, Poh-Fitzpatrick M and Wang X. Correction of erythropoietic protoporphyria (EPP) phenotype by allogeneic bone marrow transplant. Blood, 92(10), 523a, 1998, poster.
50. George J, Raskob G, **Lichtin AE**, Bussel J, Cobos E, Green D, Malone R, Rutherford C, Wasser J, TenHoor C and Nadeau K. Safety and effect on platelet count of single dose monoclonal antibody to CD40 ligand in patients with chronic ITP. Blood, 92(10), 707a, 1998, oral presentation.
51. Bolwell BJ, Wise K, Pohlman B, Andresen S, Koo A, Goormastic M, Overmoyer B, **Lichtin AE**, Miller M, Kalaycio M. CD34⁺ collection is a dynamic process. Blood, 92(10), 1998.
52. Sutkowi L, Pohlman B, Kalaycio M, Andresen S, **Lichtin AE**, Goormastic M, McBee M, DeMars D, Kephanrt E, Bolwell B. Clinical correlations of the Engraftment syndrome. Blood, 94(10), suppl 1 p.146a, 1999, poster.
53. Quintiles Research Grand Rounds, Institutional Review Board, CCF, September, 1999.

Presentations Continued:

54. CCF Myeloma Program, Pathophysiology and treatment options for lymphoma, October 6, 1999.
55. Cuyahoga Community College's Ethics Series, Ethics and Oncology, October 22, 1999.
56. CCF ASH Review, Bone Marrow Failure Syndromes, January 15, 2000.
57. Leukemia and Lymphoma Society Trustees' Education Program, Myelodysplasia, February 26, 2000.
58. Board Simulation in Hematology and Medical Oncology, CCF Internal Medicine Board Review Course, June 24, 2000.
59. CCF internal Medicine Symposium, "State of the Art - Hematology/Oncology", "Anemia", "Breast Cancer", Mexico City, November 17 & 18, 2000.
60. Responsible Conduct for Research Symposia to Clinical Investigators, CCF, 2000.

Publications:

1. Lichtin **AE**, Silberstein LE, Schreiber AD. Thrombotic thrombocytopenic purpura with colitis in an elderly woman. J. American Medical Association 1985, 255 (11); **1435-1436**.
2. Lichtin **AE**, Schreiber AD, Hurwitz S, Willoughby TL, Silberstein LE. Efficacy of intensive plasmapheresis in thrombotic thrombocytopenic purpura. Archives of Internal Medicine 1987; 147:2122-2126.
3. Lichtin **AE**, Hamburger S. Emergency management of sickle cell disease. Emergency Decisions 1988, 4(4); 36-45.
4. Lichtin **AE**. Sickle cell disease in Difficult Medical Management. WB Saunders, Edited by Robert B. Taylor, M.D., 1990.
5. Lichtin **AE**, Barthel J, Lavery I, Biscotti C: Indolent course for large cell lymphoma of ileocecal valve. Cleveland Clinic Journal of Medicine, 1991 (accepted, awaiting publication).
6. Tubbs R, Berkley V, Valenzuela R, McMahon J, Gephhardt G, Fishleder A, Nally J, Pohl M, Lichtin **AE**. Pseudogamma Heavy Chain (IgG4 lambda) Deposition Disease, Modern Pathology, 5(2), 185-190, 1992.
7. Segal GH, Mesa MV, Fishleder AJ, Stoler MH, Weick JK, Lichtin **AE**, Tubbs RR. Precursor Langerhans cell histiocytosis: An unusual histiocytic proliferation in a patient with persistent non-Hodgkin's lymphoma and terminal acute monocytic leukemia. Cancer, 70(2), 547-553, 1992.
8. Goodman JL, Horowitz H, Wolff S, Fox B, Friedman D, Shadduck R, Silber S, Lichtin **AE**, Winston D, Chandrasekar P, Powerly W, Greenfield R, Stiff P, Mangan K, Kaizer H, Shea T, Weisdorf D, How DW, Gilbert G, Buell D. Does Fluconazole prevent fungal infections in patients undergoing bone marrow transplantation? Results of a randomized trial. New England Journal of Medicine, 326 (13), 845-851, 1992.
9. Fishleder A, Bolwell B, Lichtin **AE**. "Incidence of Mixed chimerism using busulfan/cyclophosphamide containing regimen in allogeneic bone marrow transplantation". Bone Marrow Transplantation, 9, 293-297, 1992.
10. Lichtin **AE**, Anemia Work-Up: A Five Step Approach. Cleveland Clinic Journal of Medicine, 59(6), 568, 1992.
11. Kavuru M, Gadsden T, Lichtin **AE**, Gephhardt G. Hydroxyurea induced acute interstitial lung disease, Southern Medical Journal, 87(7), 767-769, 1994.
12. Budd GT, Bukowski RM, Lichtin **AE**, Van Kirk P, Ganapathi R: A phase II trial of doxorubicin and trifluoperazine in Metastatic breast cancer. Investigational New Drugs, 11, 75-79, 1993.

Publications (continued):

23. Bolwell BJ, Kalaycio M, Goormastic M, Donnley R, Andresen SW, **Lichtin AE**, Overmoyer B, Pohlman B. Progressive disease after ABMT for Hodgkins Disease. Bone Marrow Transplantation, 20;761-765, 1997.
24. **Mossad SB**, **Lichtin AE**, Hall GS, and Gordon SM. Diagnosis: Capnocytophaga canimorsus septicemia. Clinical Infectious Diseases, 24:267, 1997.
25. George CS and Lichtin AE. Hematologic complications of rheumatic disease therapies. Rheumatic Disease Clinics of North America, 23(2), 425-437, 1997.
26. Maran A, Waller C, Paranjape J, Li G, Xiao W, Zhang K, Kalaycio M, Maitra R, Lichtin AE, Brugger W, Torrence P, and Silverman R. 2',5'-Oligoadenylate-Antisense Chimeras Cause RNase L to Selectively Degrade bcr/abl mRNA in Chronic Myelogenous Leukemia Cells. Blood, 92(11), 4336-4343, 1998.
27. Bauer WM, Lichtin **AE**, Goldblum J, Conwell D, and Lashner B. Chronic Respiratory Distress, Dyspepsia, and Diarrhea: What is the Connection? J Clin Gastroenterol, 27(4): 312-315, 1998.
28. Grantham M, Einstein D, McCarron K, Lichtin **AE** and Vogt D. Littoral cell angioma of the spleen. Abdom Imaging 1998 Nov-Dec;23(6):633-635.
29. Lichtin **AE**. Idiopathic thrombocytopenic purpura: guidance amid uncertainty. Cleve Clin J Med 1998 Nov-Dec;65(10):510-514.
30. Shapiro JL, Lichtin **AE**, Sandhaus LM. Persistent polyclonal B-cell Lymphocytosis. Laboratory Medicine, 30(8), 510-513, 1999.
31. Silver RT, Woolf SH, Hehlmann R, Appelbaum FR, Anderson J, Bennett C, Goldman JM, Guilhot F, Kantarjian H, Lichtin **AE**, Talpaz M, Tura S. An evidence-based analysis of the effect of busulfan, hydroxurea, interferon and allogeneic bone marrow transplantation in treating the chronic phase of chronic myeloid leukemia: Developed for the America Society of Hematology. Blood, 94(5), 1517-1536, 1999.
32. Wang X, Yang L, Kurtz L, Lichtin **AE**, DeLeo V, Bloomer J, Poh-Fitzpatrick MB. Haplotype analysis of families with erythropoietic protoporphyria and novel mutations of the ferrochelatase gene. Journal of Investigative Dermatology, 113(1), 87-92, 1999,
33. Karanes C, Kopecky KJ, Head DR, Grever MR, Hynes HE, Kraut E, Vial R, **Lichtin AE**, Nand S, Samlowski W, Appelbaum FR. A phase III comparison of high dose Ara-C (HIDAC) vs. HIDAC plus mitoxantrone in the treatment of first relapsed or refractory acute myeloid leukemia, Southwest Oncology Study Group. Leukemia Research, 23, 787-794, 1999.
34. George R and **Lichtin AE**. An elderly man with intermittent right arm numbness and polycythemia. Cleveland Clinic J Med, 67(4), 250-256, 2000.

Publications (continued):

35. Bolwell EJ and **Lichtin AE**. Board simulation I: Hematology and Medical Oncology. In: Stoller JK, Ahmad M, Longworth DL, eds. The Cleveland Clinic Intensive Review of internal Medicine. 2nd ed. Philadelphia: Lippincott Williams & Wilkins, 2000. Chapter 28. 319-335.

CV.AEL
03/20/01

Remaining pages under seal until
further order of the Court or agreement
of the parties.

*The Cleveland Clinic
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*The Institutional
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