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IN THE COURT OF COMMON PLEAS

CUYAHOGA COUNTY, OHIO

MARY LOU ZIMMERMAN, et al.,

Plaintiffs,

-vs- JUDGE BURNSIDE CASE NO. 399411

CLEVELAND CLINIC FOUNDATION, et al.,

Defendants.

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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.

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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 probablytake 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.

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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 dulysworn, 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. Okay7

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 feei 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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the IRE?
A. No.
Q. What were the issues in those other depositions; what was the subject matter of the other depositions?
MR. PARKER: Objection. You can answer.
A. A patient of mine was suing his place of employment because he felt he developed his hematologic disorder by exposure, so I gave a deposition in that case.
The second one was a patient with an extremely rare fungal infection who died here, and we made the diagnosis very close at the point of death and so the family took action.
Q. What have you done to prepare for your deposition today?
A. I've talked to Mike Meehan and Mr. Marker.
Q. Parker?
A. Parker, yes, sorry. And that's it.
Q. Have you reviewed any documents to prepare for your deposition?
A. Not really.
Q. Have you reviewed any in anyway, looked at anything?

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

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

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

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

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

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

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

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consent present. The board would review it, it would either table it or pass it or reject it.
Q. Are the investigators or co-investigators involved in presenting that to the board?
A. Usually not.
Q. So it's a written submission?
A. Usually.
Q. And minutes are kept of the IRB meetings, are they not?
A. Uh-huh, yes.
Q. Thank you. Do you know what the record retention policy is here at the Clinic?
A. I honestly don't know.
Q. For board minute meetings?
A. I don't know.
Q. Board meeting minutes.
A. That is the type of question I would turn to Dan Beyer and ask him.
Q. Did Dan Beyer work in his position back in the late '80s?
A. No.
Q. Do you know who had that position?
A. Late '80s --we did not have an executive director of the IRB until 1999.
Q. Who would have served in that capacity; who would

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

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Q. What were the results of -- strike that.
What happened as a result of that study, was it published?
A. I don't know.
Q. Who would you go to to find that out?
A. Probably Dr. Stagno or Dr. Hassenbusch. To be honest with you, I thought Dr. Hassenbusch was the principal investigator of this. When we found this sheet of paper, I saw Dr. Stagno's name.
Q. Stagno?
A. I was surprised because my remembrance was Hassenbusch was the one who was the PI, but I was wrong.
Q. Stagno is a psychiatrist?
A. Correct.
Q. And Hassenbusch was a neurosurgeon?
A. Correct.
Q. Was written consent required as part of that study?
MR. PARKER Objection.
A. I honestly don't remember.
Q. Have you ever approved a -- strike that.
Has the IRB ever approved of a research study where written consent was not required for a surgical procedure?
MR. PARKER Objection.

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

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and the IRB in its mind would waive written informed consent.
Q. Can we agree that brain surgery, where you are destroying parts of the brain in an attempt to treat something like OCD, is a type of surgerythat would require written consent?
A. Yes.
Q. And why is that?
A. I don't think that such a procedure would ever have those sorts of stipulations for waiver of written informed consent.
Q. And what's the purpose of having a written informed consent?
A. The purpose of written informed consent, you would have to ask the drafters of the 45 CFR 46 what the purpose of written informed consent is, but my interpretation of it is, you know, to have research subjects be informed of what research they're about to undergo.
Q. And it assures that they have been adequately informed of the risks, benefits and alternatives to the procedure?
MR. PARKER Objection.
A. I would just refer you to the language in 45 CFR 46 about what elements of informed consent are

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necessary.
Q. Well, informed consent is an important part of any research project that comes before the IRB, isn't it?
A. Correct.
Q. What is your understanding of what is required for informed consent?
A. As stated in 45 CFR 46, there has to be information on research, risks, benefits, alternatives, cost considerations, aspects of voluntary participation, something related to what to do in case of research related injuries. I might be missing something, but there's about ten elements that have to be covered by research subjects in participating research.
Q. And what is the advantage *to* having that be in writing as opposed to simply being verbally told to a patient?
A. Say that question again.
Q. Sure.
- - - -
(Thereupon, the requested portion of the record was read by the Notary.)
- - - -
A. I'm not sure that there's an advantage of writing or verbal. The federal regulations criteria that IRBs

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have to exercise, whether a written informed consent is necessary or not, some written informed consent documents are long and voluminous and some patients may not understand everything there, but we, as the IRB, try to make it as much in layman's language as possible.
MR. PARKER: Let me just insert a statement or comment or objection, however you want to phrase it. I just want the record to reflect that the conversation that has been occurring over the last few minutes about informed consent and written informed consent are in the context of IRB review of research activities.
MR. LINTON: I'm going to object and move to strike that comment by counsel.
Q. Doctor, are you aware of any other psychosurgical procedures which have been submitted at anytime during your tenure to the IRB besides the Stagno study?
A. To the present time?
Q. Yes.
A. Yes.
Q. And that's the Rezai study?
A. Yes.

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Q. Any other psychosurgical procedures or studies that have been submitted to the IRB, that you're aware of, besides those two?
A. I can't remember any.
Q. Do you recall at any time --strike that.
Do you know Dr. Gene Barnett, neurosurgeon?
A. I know him.
Q. Do you recall being involved at all in the IRB review of his study performing psychosurgery on terminal cancer patients to try to relieve pain?
A. I don't remember.
Q. I don't know if, in fact, it was submitted. I just want to know if you have any recollection of that issue or that study being submitted to the IRB?
A. No.
Q. Help me out just in terms of basics. Why is there an IRB at The Cleveland Clinic?
A. Any medical facility that wants to do research has to have an IRB.
Q. It's required by law?
MR. PARKER: Objection.
A. Yes.
Q. Why is that?
A. There are federal regulations that say this. I'm not sure if that's a law or whether that's a federal

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regulation.
Q. When I use the word law, I include a federal regulation.
A. Okay.
Q. So an IRB is required by federal regulation at any institution doing research, correct?
A. Yes.
Q. And the purpose of an IRB is to protect human subjects that are involved in that research, correct?
A. Involved in research.
Q. Right. And your --that's the ultimate purpose of an IRB, correct?
A. That's the purpose of an IRB.
Q. Is to make sure that the subject matters are protected during research?
A. The research subjects are protected.
Q. Okay. That is the people that are willing to undergo the research project?
A. The peopie who are research subjects.
Q. Okay. The people that are going to be the guinea pigs in a research project?
MR. PARKER Objection.
Q. I mean, if we break it – correct?
MR. PARKER: Objection to the

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inflammatory language. You can answer, if that is a question that you can provide a fair answer to.
MR. MEEHAN: If he can't answer, he can't answer, Alan.
A. The IRB is designed to protect research subjects who are undergoing research.
Q. And your job, as head of the IRB, among other things, is to make sure that those subjects are protected in the research?
A. Just repeat the question.
Q. Sure. Part of your job as head of the IRB is to make sure those research subjects are protected in the research?
A. Yes.
Q. And in fact, it's important that you act independently of the institution that employs you, correct?
A. Yes.
Q. The idea is that you are to act independentlyfrom the interests of the institution in perhaps carrying out that research?
MR. PARKER: Objection. What do you mean he acts independently?
Q. Well, do you not understand the question, Doctor?

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

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A. Yes.
Q. So whenever the IRB feels, for whatever reason, they're not qualified, they can get those qualified to review the project, correct?
A. Repeat the question again.
- - - -
(Thereupon, the requested portion of the record was read by the Notary.)
- - - -
A. *Yes.*
Q. So if -- did the Clinic go outside its then constituted IRB to obtain experts on an ad hoc basis to review the Stagno study?
MR. PARKER: Objection. If the question is regarding the Stagno study, you can answer.
A. I honestly don't remember.
Q. Is one of the purposes of the IRB to also approve the research protocols that are submitted?
A. Say it again.
Q. Sure. What are the responsibilities of the IRB?
A. To oversee research.
Q. Does that include approving research protocol?
A. Yes.
Q. Does that include making sure that there is a

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scientific foundation for the research?
A. Yes.
Q. That the study is valid, the study --
A. I would say --
Q. The research protocols are valid?
A. Yes.
Q. And that the statistical analysis is correct?
A. Correct.
Q. And if, for whatever reason, it is incorrect, the IRB can make recommendations that it be changed before approval is given, correct?
A. Correct.
Q. And you're familiar with statistics, are you not, as part of your education, training and experience?
A. I am not a board certified statistician. I have a rudimentary understanding of statistics.
Q. You certainly know enough in order to approve the research protocol that's submitted to the IRB?
A. Oftentimes I will turn to other members of the IRB who know more about statistical design *to* get their input.
Q. Well, for example, in your own practice you have a specialty in oncology?
A. Hematology/oncology.
Q. And if there's a new form of cancer that's out there

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

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MR. PARKER: No, he said he can't answer that question. Now, if you want *to* ask it --
Q. Would that be a statistically valid statement?
A. I can't answer that. I don't know enough about statistics to say.
Q. Well, do you recommend treatment for your own patients?
A. Uh-huh, yes.
Q. And when you do that, do you quote statistics for treatment based on your understanding of valid studies and reports and literature?
A. I do.
Q. Do you ever quote statistics to patients when there are not success rates that have been published in the literature or subject to reliable studies?
A. No.
Q. Why not?
A. I'm guided by the reliable studies.
Q. You don't just independently add up statistics from different reliable studies and present those to the patient, do you?
MR. PARKER: Objection.
A. Say the question again.
Q. Sure. If there was a study that you relied on for

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one form of treatment with a statistic and a study showing another different type of treatment with a different statistic, would you simply combine those two treatments for a patient when that had not been subject to a reliable study or reports in the literature?
A. Again --
MR. PARKER: Objection.
A. -- it's hypothetical. I don't see how I can answer that question.
Q. Have you ever done that in your practice?
A. Cancer and hematology -- in cancer patients and hematology patients we don't -- we're not confronted by this type of question.
Q. You're not confronted with questions regarding treatment and what are the best treatment options for your patients?
A. We are.
Q. And you're not involved in trying to recommend different treatment options to a patient?
A. We do.
Q. And when you do that, you base it on statistics as reported in the literature or reliable studies?
A. Correct.
Q. As chairman of the IRB, would you approve a

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procedure for which there were no reported success rates or which had no reports in the literature?
MR. PARKER: Objection. Calls for speculation.
A. Say the question again.
Q. Sure.
- - - -
(Thereupon, the requested portion of the record was read by the Notary.)
- - -
A. As chairman of the IRB, I never approve something myself. It's up to the whole board to approve something.
Q. Would you recommend its approval? You get a vote, do you not?
A. I do.
Q. Would you vote for its approval?
MR. PARKER: Objection. The foundational question remains speculative. You can answer it, if you can do so.
A. What was the foundational question again?
- - - -
(Thereupon, the requested portion of the record was read by the Notary.)
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A. Yes.
Q. Under what circumstances?
A. We would have to see a protocol, we'd have to see what medical knowledge there was leading up to the point of the protocol, we'd have to see the rest of the protocol to make a decision whether to approve it.
Q. How do you define research in terms of what falls within IAB review?
A. There's a definition of research, which I was hoping to memorize, but it's in here. It's systematic investigation. It's --
Q. Are you looking for the definition section?
A. There's some sheets that come after this. Maybe it's -- it's in 45 CFR 46. Give me that.
MR. MEEHAN: This is my document. I'm a lawyer.
A. It's not in here. You took it away. There was something behind here earlier this morning.
MR. PARKER: It's in the CFR?
A. CFR 45, 46. Systematic investigation designed to lead to generalizable knowledge. But there's some other subclauses in there which I can't remember off the top of my head, and I would feel more comfortable having it in front of me.

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

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

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an objection. You're asking him for any institutional -- I forget your term, any institutional whatever. Dr. Lichtin can only speak for areas, obviously, in which he's knowledgeable. He can't speak for the institution.

MR. LINTON: I understand.

Q. Are you aware of any institutional safeguards to protect patients from any surgical procedures?

MR. PARKER Objection.

A. I don't know how to answer that. I'm not aware of -- I don't know how to answer that.

Q. Why don't you know how to answer it; is it confusing to you?

A. I'm not confused.

Q. Are there medical practices committees set up to approve and safeguard against experimental surgery here at Cleveland Clinic7

MR. PARKER: Objection.

A. I don't know.

Q. Are you aware of any?

A. i know there are committees that look at surgical practice, but I'm not aware of anything like what you're describing.

Q. That is any committee that would approve an

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experimental surgical procedure before it's performed on a patient?

MR. PARKER: Objection.

Q. You're not aware of that?

MR. PARKER: Go ahead and answer the question.

A. No, I'm not aware of it.

MR. PARKER: And may I ask what you mean by experimental procedure?

Q. Experimental procedure, one that is for which there has been no scientifically valid study nor reports in the literature.

MR. PARKER Okay. That's not a question, but i want a clarification for the purposes of this record as *to* whit you mean.

Q. What do you understand experimental procedure to mean?

A. Well, I feel I have an understanding of research.

Q. Okay.

A. But if a doctor, in his or her practice of medicine, wants to try something on a patient that does not mean that's research. You may call that experimental, but the doctor may view that as his practice of medicine.

Q. Well, are there any guidelines available to

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determine whether it is experimental or not?

A. There are guidelines that determine the definition of research.

Q. In your judgment, is research different than experimentation?

MR. PARKER: Objection. I think a part of the problem here is he has said again and again and again that the term experimentation is not a term that has a specific meaning to him, so I don't know how he can answer your question. If you can answer it, feel free to do so.

A. No.

Q. Are there ever times that innovative therapies are submitted to the IRB for approval?

A. When the innovative therapies are a part of a research protocol they can be, they are, yes.

Q. So if a doctor is doing innovative therapy that he also wants to study, then that's something that would be submitted to the IRB?

A. Correct.

Q. And that would then require ail the IRB safeguards to be followed7

A. Correct.

Q. And make sure that there is a scientifically valid

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basis for the research, correct?

A. Correct.

Q. As well as to make sure that the subjects of that innovative therapy are protected7

A. Correct.

Q. Should psychosurgery at The Cleveland Clinic be subject to IRB review?

A. If it's research, yes.

Q. What if it -- in order for it to be researched, does it have to be published?

A. No.

Q. Does it have to be reported?

A. No.

Q. Does a study even have to be concluded?

A No,

Q. Is there a limited number -- strike that.

Is there a minimum number of patients that have to be studied in order for it to be researched?

A. No.

Q. Can there be research on a singie patient7

A. Yes.

Q. Who decides if it's research?

A. The physician who is about to do the procedure, if the intention is that this is research and I want to contribute to generalizable knowledge, they would

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have to submit to an IRB. if the physician decides I just want to treat this one patient in what they feel is an innovative but potentially helpful way, it's up to the physician and they don't have to come to IRB.
Q. And if there are mixed motives, should the physician err on the side of submitting it to the IRB for approval?
MR. PARKER: Objection to form.
A. if there's any hint of an intention to do research, it has to come to the IRB.
Q. So the answer to my question is yes?
A. You used the word mixed motives. I would say if there's an intention to do research.
Q. In any --
A. If any part of the consideration of the doctor is that they are about to propose research, then it should come to the IRB.
Q. So that if there's a five percent intention to do research and --
A. If there's a one millionth percent to do research.
Q. It needs to come to IRB?
A. It's an intention, in my mind.
Q. Even if the doctor does not then have a present intention to publish the results of the research?

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A. I can foresee -- well, say the question again. I'm sorry.
Q. Even if the physician at the time does not have a present intent to actually publish the results of the research? Bad question.
MR. PARKER Yeah.
Q. If a physician wants to treat a patient with an experimental procedure and also wants to study the effectiveness of that experimental procedure, then that shouid be submitted to the IRB?
MR. PARKER: Objection to the terminology. You can answer.
A. Again, you're using the word experimental, and there's no regulatory definition of the word experimental.
Q. Well. is there one for innovative?
A. No.
Q. Then why are you using the word innovative as opposed to experimental; is there some recognized definition for innovative?
A. Not in 45 CFR 46.
Q. If a doctor wants to use an innovative therapy both to treat his patient as well as to study the effectiveness of that innovative therapy, that should be submitted to the IRB for approval?

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

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can answer that, if you can answer it.
A. A protocol, a research protocol.
Q. Have any innovative therapies been submitted to the IRB for approval, in your experience, that do not involve research?
A. I can't remember a specific instance, but people have submitted things to the IRB and we've reviewed it and said this is not research and therefore we don't have jurisdiction. I can't even give you an example, but I believe that's occurred.
Q. What is done to check the science or the medicine of the proposed research when it's submitted to the IRB?
A. There's enough scientific expertise around the table that can handle most things. If we are unsure of the science, we will ask for other doctors at the Clinic to look at it.
Q. So you'll go beyond the science that's submitted by the physician?
A. Yes.
Q. To independently verify that7
A. Yes.
Q. And would you allow a procedure which -- strike that. Would you approve an IRB -- strike that.
MR. PARKER: While you formuiate your

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question, why don't we take five minutes. We've been at it an hour.

MR. LINTON: Sure.

- - - -

(Thereupon, a recess was had.)

- - -

Q. Dr. Lichtin, you're familiar with The Cleveland Clinic's IRB policies and procedures, correct?
A. If I had a question, I'd look it up.
Q. But you've worked with the policies and procedures of the IRB throughout your tenure on the board, correct?
A. From '99 on, yes.
Q. You didn't review them before '99?
A. We didn't have they have before '99.
Q. What did the IRB follow in making its decisions if there were no policies and procedures in place before '99?
A. We followed the CFR 45, 46 and FDA regulations. We used the reguiatory language that was disseminated by the federal authorities. Most everything here is a reiteration of those regulations anyway.
Q. Was the Belmont report also something that was followed by the IRB before there were formal policies and procedures?

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A. The Belmont report is an expression of ethics, and we certainly agreed to what it says.
Q. it's something --
A. But it doesn't have regulatory teeth.
Q. But it's something that you certainly would consult and acknowledge as a guideline or authority in helping to resolve ethical issues in an IRB context?
A. Correct.
Q. So I'm clear, there was not an IRB policy and procedure manual in place in 1998, correct?
A. Not to my remembrance.
Q. Does your policy and procedure manual allow for IRB review of anything beyond research as defined in the CFR?
A. I don't think so. I'd have to look it up. I don't think so.
Q. The Stagno study *of* cingulotomy was completed in 1994, correct?
A. Uh-huh, yes.
Q. And that was for cingulotomy and the treatment of intractable OCD?
A. Yes.
Q. If a physician wanted to research cingulotomy coupled with another surgical procedure like

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capsulotomy, that would have required another IRB review, correct?
A. If it was research, yes.
Q. And that would require, then, the IRB process -- strike that, would require separate submissions to the IRB, correct?
A. No.
Q. What would a physician have to do to comply with the requirements of IRB review if he was studying cingulotomy plus another surgical procedure like capsulotomy to treat OCD?
A. The investigator could amend a protocol so you can have an established protocol and just put an amendment to it as opposed to submitting a whole new protocol.
Q. But an additional amended protocol at the very least would have to be submitted, correct?
A. Correct.
Q. And if a different physician wanted to study that, could he ride the coattails of the earlier study and simply follow an amended submission, or would it have to be a new submission?
A. He or she could try to do that, but the IRB might look at that amendment and say this is a whole new protocol, you have to submit a whole new protocol.

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

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Q. The study identified on Exhibit *6.*
A. *Yes.*
Q. What was your involvement?
A. Chairman of the IRB.
Q. And what did you do as chairman of the IRB to approve Dr. Rezai's study?
A. I supervised the discussion about the protocol, we had the investigators come to the IRB to discuss the protocol in more detail.
Q. Why is that?
A. Because it's dramatic.
Q. In what way?
A. The same way as I was talking about how dramatic the previous one was.
Q. Dramatic in terms of doing anything -- strike that.
How is this dramatic like the cingulotomy?
A. Involved with neurosurgery for a psychiatric disease.
Q. Did you review the original submission for Dr. Rezai's study?
A. I remember looking at it. I forget who the primary reviewer was, but I do remember looking at it, yes.
Q. And what materials were submitted in order to obtain IRB approval for Dr. Rezai's study?
MR. PARKER Let me reenter my

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

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A. Correct.
Q. And do you maintain copies of those records in your file?
A. The IRB office does.
Q. Is that Beyer again that would be in charge of that file?
A. Correct.
Q. Do you recall if there was any reference in the submission to other forms of neurosurgical treatment for OCD besides the electric stimulation?
A. I don't remember. I would presume there would be.
Q. Was there any consideration given to Dr. Rezai's study to the capacity of the patients to give proper informed consent in the sense that these were psychiatric patients, obviously serious psychiatric patients who would be considering neurosurgical treatment for their disorder?
MR. PARKER: Objection.
A. *Yes.*
Q. And were there any additional safeguards that were provided because of that patient population?
MR. PARKER: Objection.
A. I believe **so.**
Q. And what additional safeguards were implemented?
MR. PARKER: Objection.

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

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dates to a project.
Q. The study number IRB 4498, that's the file number or study number here?
A. Correct.
Q. Does that mean it's the 4,498th study?
A. I don't think so. There's a numbering system that the IRB office has generated over the years, but this is not the 4,498th study that the IRB has done.
Q. Tell me what you can remember being discussed at the board meeting when Dr. Rezai was there to answer follow-up questions or concerns the IRB had about his proposed study.
MR. PARKER Objection.
A. I remember many aspects of discussion pertaining to FDA regulations, these electrodes and pacemaker, did they comply with FDA criteria in getting an investigative device exemption. I remember discussion of the consent process, the determination whether the patient is competent to give consent.
Q. What do you remember about the second topic, about the consent process and what's required in terms of the patient's competency to give consent?
A. I'd really have to look back at the file to get the exact nature of what we said. I don't have our

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judgment about the project in front of me.
Q. What would you have to look to to find that, is that the --
A. 4498, the file.
Q. Were there any discussions about the past results at The Cleveland Clinic with psychosurgery?
A. I don't remember.
Q. Any discussion about past problems with psychosurgery at The Cleveland Clinic?
A. I don't remember.
Q. Any discussions about the advantage of the electric stimulation over conventional neurosurgery?
A. I honestly don't remember.
Q. Did Dr. Barnett, Gene Barnett, the neurosurgeon, attend any of these IRB meetings?
A. Not to my remembrance, no.
Q. Have you ever had any discussions with him about psychosurgery?
A. No.
MR. LINTON: Alan, is there some reason why we haven't received ail the other records that were requested from Dr. Rezai's study?
MR. PARKER if there are other records, I'll look into it for you.
Q. Well, what other records would exist, Doctor, for

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Dr. Rezai's study?
A. A copy of his protocol.
Q. Minutes of the meeting --
A. Yes.
Q. --would exist?
A. Yes.
Q. What additional documents; correspondence?
A. Correct.
Q. You talked about your recommendation or your judgment; is that contained in a separate document?
A. When I say recommendation or judgment, I mean when we have certain things that we want them to change that will be in a letter to the investigator.
Q. Would there, likewise, be any research that would be submitted: would that be part of the research protocol?
A. Correct.
Q. There would be the written consent procedures and written consent forms?
A. Correct.
Q. Any other documents that would be part of that study?
A. My remembrance is there may be something related to communications with the FDA about the

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device.
Q. Anything else?
A. No.
Q. There, likewise, at one time would have been similar documents with respect to the Stagno study, correct?
A. I believeso.
Q. That would be research protocol, consent procedures, written consent forms, correspondence and minute meetings?
A. Correct.
Q. Excuse me, minutes of the meetings?
A. Correct.
MR. LINTON: Give us just a minute, if you will.
- - - -
(Thereupon, a discussion was had off the record.)
- - - -
MR. LINTON: Subject to additional questions on the documents that we have not yet received, and I think we'll probabiy be fighting over, that's all the questions I have at this time, Dr. Lichtin. Thank you very much.

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THE WITNESS: Okay.
MR. PARKER We'll read and sign.

ALAN E. LICHTIN, M.D.

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CERTIFICATE

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

I Laura L Ware, a Notary Public within and for thk 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.

IN THE COURT OF COMMON PLEAS
CUYAHOGA COUNTY, OHIO

MARY LOU ZIMMERMAN, ETC.	)	**CASE NO. 399411**
	)	
Plaintiffs,	)	**JUDGE JANET R. BURNSIDE**
	)	
-VS-	)	
	)	
THE CLEVELAND CLINIC FOUNDATION, et al.	)	**PLAINTIFFS' SIXTH REQUEST FOR PRODUCTION OF DOCUMENTS**
	)	
Defendants.	)	

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)
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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
1I 3 St. Clair Avenue, NE
Cleveland, Ohio 44114-1841

MARK W. RUF (#0047100)

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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.

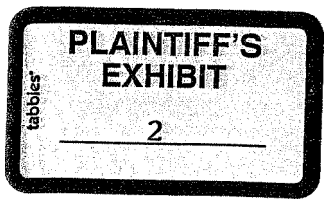
Without waiving the objection, the IRB in 1998 operated pursuant to policies and procedures set forth in 45 CFR 46 and The Belmont Report.

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.

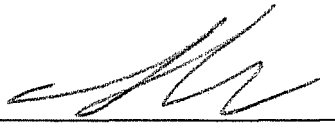
RESPONSE: Attached.

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.



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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 **I).**	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	**PI1** D	None	None
Michael J. Meehan	J D.	None (Law)	Employee
Linda Lewickl	Ph D , R N	Nursing Research	Employee
Gregory Plautz	M D	Surgical Research Center	Employee
Jeffrey Ross	M D	Neuroradiology	Employee
Kenneth Shormock	Pharrn 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	Emptayee
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

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 SHADED)	HIGHEST DEGREE EARNED	SCIENTIFIC SPECIALTY	AFFILIATION WITH INSTITUTION	SCIENTIFIC/NON-SCIENTIFIC
Alan Lichtin (Chair)	MD	Hematology and Medical Oncology	Employee	Scientific
Alternate - Jay Ciezki	MD	Radiation Oncology	Employee	Scientific
Michael Lauer (Vice Chair)	MD	Cardiology	Employee	Scientific
Alternate - Susan 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 Bedocs	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 Wirkus	PhD	Philosophy/Ethics	Community Representative	Non-Scientific
Michael J. Meehan	JD	General Counsel	Employee	Non-Scientific
Jeffrey Ross	MD	Radiology	Employee	Scientific
Kenneth Shermock	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

MULTIPLE PROJECT ASSURANCE OF C[illegible]NGE WITH DHHS REGULATIONS
FOR PROTECTIONS OF HUMAN RESEARCH SUBJECTS

IRB Name: Institutional Review Board of the Cleveland Clinic Foundation, 9500 Euclid Avenue, Wo2, Clevoland, 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. Ucala	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 Anasthesia	Employee	Scientific
Jean Pierre Yard	MD	Cardiothoracic Anasthesia	Employee	Scientific
Ronald Bukowski	MD	Hematology and Medical Oncology	Employee	Scientific

OFFICE OF THE INSTITUTIONAL REVIEW BOARD: Paul Papagni, JD, Executive Director
Michele 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 Lichtin (Chair)	MD	Hematology/Oncology	Employee	Scientific
Alternate - Joseph Frolkis	MD, PhD	Preventive Medicine	Employee	Scientific
Michael Lauer (Vice Chair)	MD	Cardiology	Employee	Scientific
Alternate - Sasan Ghaffari	MD	Cardiology	Employee	Scientific
Linda Lewicki (2nd Vice Chair)	PhD, RN	Nursing Education & Research	Employee	Scientific
Alternate - Lorraine Mion	PhD, RN	Nursing Education & Research	Employee	Scientific
Nita Marie Bedocs	MSN, 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 Laird/an	PhD	Community Representative	None	Non-Scientific
Alternate #2 - Brenda Wirkus	PhD	Community Representative	None	Non-Scientific
Alternate #3 - Pat Mason	PhD	Community Representative	None	Non-Scientific
Michael J. Meehan	JD	General Counsel	Employee	Non-Scientific
Alternate - Ian Serkey	JD, RN	General Counsel	Employee	Scientific
Jeffrey Ross	MD	Radiology	Employee	Scientific
Alternate - Jay Clezki	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 BILYUE	RN	OMBUDSMAN	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 dared 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

Dare closed to accrual:

Date first approved: October 5, 2001

Date last Action: October 5, 2001

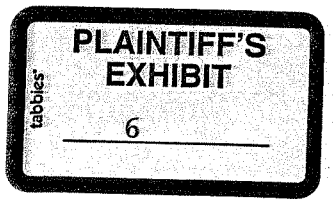
Date purged:

Date suspended:

Dare terminated:

Deadline suspension:

Deadline termination:



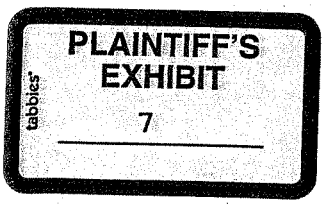
STUDY INFORMATION

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. Lichtor

TO: Stagno, Susan, P57

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

RE: RPC 3032 "Cingulatomy 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
1992-1996 Appointed Hematology representative, 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 Resarch Ethics National Association (ARENA)

Principal Investigator:

1. CCF PI for cooperative grant with Leslie Schover Ph.D.. lnterative media on banking sperm before cancer therapy.

2. P I – 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 1997-present	Institutional Review Board Adult and Pediatric, First Vice-Chair 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	Reelected, 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, Baucco 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, Baucco 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, Licktin 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, Danniey R, Goormastic ivi, Yanssens T, Baucco 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 Eichtin 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, Baucco 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 sufficientto sustain long term hematopoiesis following myeloablastive 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 Kaiaycioglu 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 aisorder after cardiac transplantation: iviuiiipie myeloma 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 B_{12} 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, Pohirnan B, and Kalaycio M. Late relapse after ABMT for Hodgkin's Disease. Blood, 88(10), p 122a, 1996.

24. Andrish S, Hoeltge G, Tuason L, and Lichtin **AE.** Clinical characteristics *of* patients with ▮1q23 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 Kaiaycio 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. 21b.

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 prosepetive cross-sectional study to characterize selected autoimmune (AI) markers and report the incidence of antithrombopoietin antibodies (αTPO) 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 I, 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 5, **Lichtin AE,** Andresen S, Burwell R, Sands K, Koo A, Owen N, Baucco **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, Baucco 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, Aprii 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 A**E. 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, TenHoc r 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, Goioirmastic 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), suppll 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 Synaromes, 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.

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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, Valenzueia 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, Fishieder 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**, Gephardt 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.

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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 Transplatation, 20;761-765, 1997.

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30. Shapiro JL, Lichtin **AE,** Sandhaus LM. Persistent polyclonal B-cell Lymnphocytosis. Laboratory Medicine, 30(8), 510-513, 1999.

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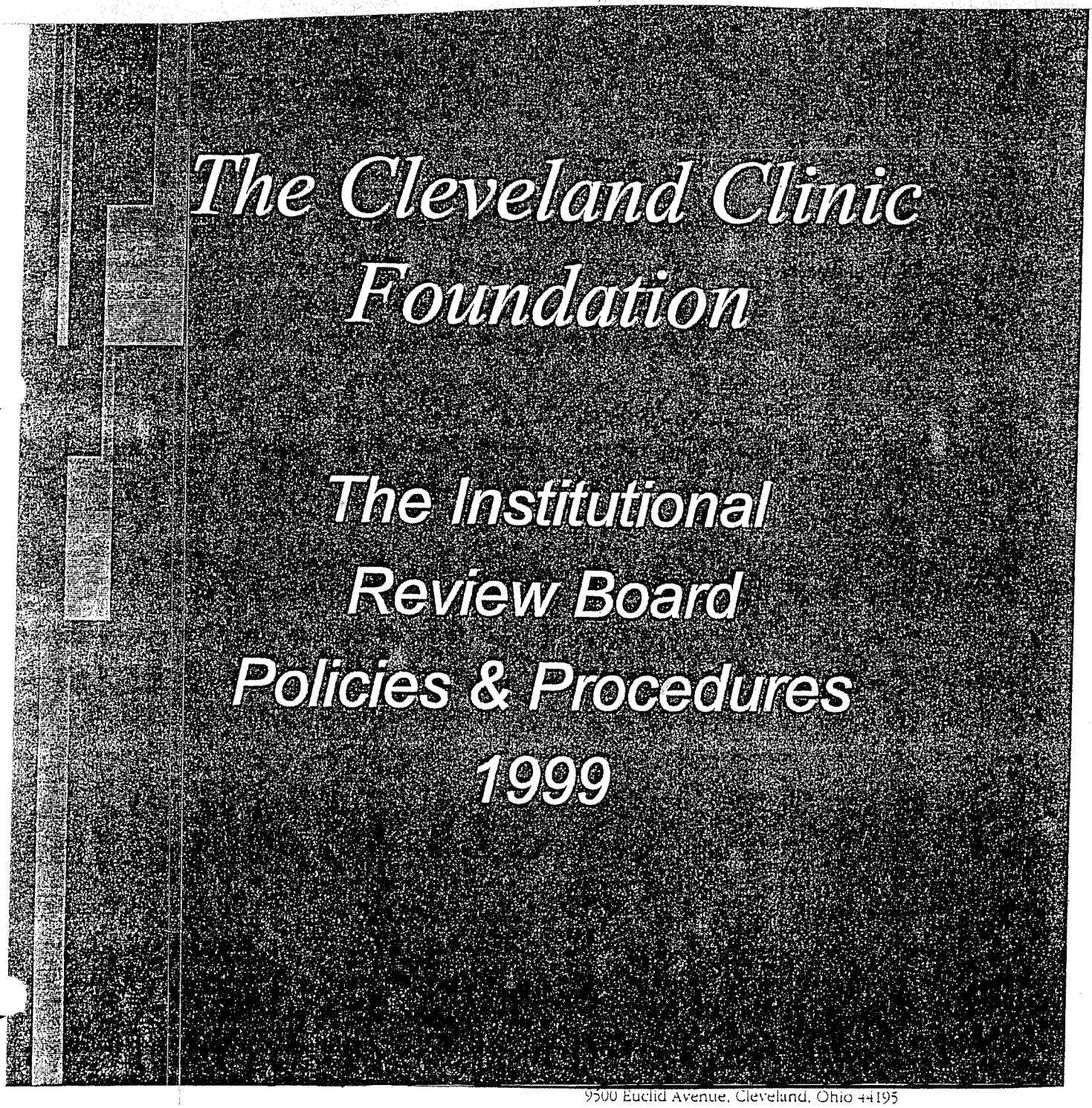

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