

# **UCLA Stroke Study Network**

924 Westwood Boulevard, Suite 300  
Los Angeles, CA 90024  
310-794-0591 Fax 310-794-0599

2524 03 MAY 20 03

May 05, 2003

Dockets Number 95S-0158  
Dockets Management Branch (HFA-305)  
Food and Drug Administration  
1242 Parklawn Drive  
Room 1-23  
Rockville, MD 20587

**RE: Waiver of Informed Consent, Dissemination of Information  
Concentric Retriever System - G030068**

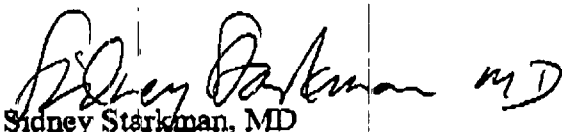
To Whom It May Concern:

In response to a letter dated April 18, 2003, The University of California at Los Angeles Medical Center, is hereby submitting information in conformance with 21 CFR 50.24(a)(7)(ii). Appropriate documentation concerning public disclosure to the communities in which the clinical investigation is being conducted is included with this letter.

As required, this is being submitted in triplicate to the IDE Document Mail Center and one copy is being submitted to the Docket Management Branch.

If there are any questions relating to this submission, or if any additional information is required, please contact me directly at 310-794-0594.

Sincerely,



Sidney Starkman, MD  
Professor of Emergency Medicine and Neurology  
University of California at Los Angeles  
924 Westwood Blvd., Suite #300  
Los Angeles CA 90024  
Tel: 310-794-0594  
Fax: 310-794-0599  
E-mail: [starkman@ucla.edu](mailto:starkman@ucla.edu)

95S-0158

RPT 9

University of California, Los Angeles

**PUBLIC MEETING INVITATION**

**MONDAY, AUGUST 12, 2002 7:00 P.M.**

All interested individuals are invited to attend a public meeting to discuss research studies being conducted at UCLA Medical Center which are designed for people who have just suffered a stroke.

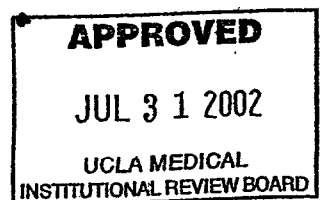
The purpose of this public meeting is to explain the research procedures, risks and benefits and the need to enroll patients into the studies without their consent. You will be invited to ask questions and make comments during the meeting.

We would like to hear from you.

**REFRESHMENTS WILL BE SERVED at 6:30 P.M.**

**FREE PARKING on UCLA Campus - Westwood Blvd just North of LeConte, first right off of Westwood Blvd. You will be directed to the meeting in the Auditorium in the NPI Building**

For more information call Judy Guzy 310-794-0591  
or e-mail <jguzy@mednet.ucla.edu>



Dear :

Federal regulations and California law allow researchers to conduct emergency room clinical research with individuals that cannot provide legally effective informed consent if the Institutional Review Board (a medical ethics research committee) for that institution finds that the study fulfills the regulations for waiver of informed consent for emergency research (title 21 Code of Federal Regulations part 50.24). One of those conditions is the requirement to provide public disclosure of the research and community consultation with representatives of the communities from which subjects will be drawn.

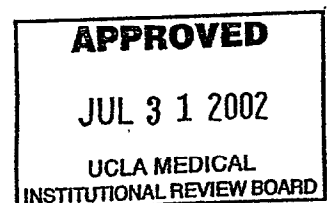
Researchers at UCLA will hold a public meeting on Monday, August 12, 2002 at 7:00 P.M. to provide information to the public regarding their emergency research studies and to obtain feedback from the attendees.

Since the meeting will occur shortly, we request that you post, distribute, or announce this notice as soon as possible.

If you have any questions regarding the public meeting or request additional information, please contact Judy Guzy, RN at 310-794-0591 or e-mail <jguzy@mednet.ucla.edu>.

Thank you for your time.

UCLA IRB# 01-02-003-02A  
Expiration Date: March 19, 2003



# UCLA Stroke Study Network

924 Westwood Boulevard, Suite 300  
Los Angeles, CA 90024  
310-794-0591 Fax 310-794-0599

Aug 13, 2002  
~~July 29, 2002~~

Robert Figlin, MD, Chairperson  
Office for Protection of Research Subjects  
Medical Institutional Review Board 2  
2107 Ueberroth Building  
Campus Mail Code 169407

RE: Request to Provide for Additional Information Prior to Issuing An Approval Notice  
UCLA IRB #01-02-003-02A  
Mechanical Embolus Removal in Cerebral Ischemia (MERICI) (Results of August  
12 Community Meeting)

Dear Dr. Figlin,

We are delighted to report that we have completed the Community Notification fully as described in the plan and then some. We had a very large Community announcement of the planned Community Forum for Community Consultation held at NPI Auditorium on August 12th at 7pm. We feel that the program was enormously successful in communicating and consulting with the diverse Community representatives who attended. We conducted the program as planned and communicated with Steven Peckman. Since this was such a comprehensive event and the Stroke Trial Community Advisory Board participated, we wish to request that this meeting serve as the first meeting of the Board.

Total Number of Surveys Completed:

1. Has the study been explained so that you understand the risks and possible benefits of the stroke treatment?  
Yes 178  
No 2
2. Do you understand that patients will be enrolled without their consent, or the consent of a family member, at least initially?  
Yes 177  
No 3
3. Do you understand that patients will be treated and if family or legally authorized representative is reached, they will have an opportunity to withdraw the patient from the research or approve continued participation?  
Yes 176  
No 4

4. Was it made clear that all patients will receive the standard care for acute stroke, whether or not they take part in this research study?  
Yes 178  
No 2
5. Would you be willing to participate in this study or have a family member participate without your consent?  
Yes 166  
No 14
6. In view of what you have learned here, are you willing for this study to be done in your community?  
Yes 172  
No 8
7. If you answer no to either #5 or #6, please tell us what changes you would suggest.

8. Ethnicity:

Hispanic or Latino	12	
Not Hispanic or Latino	168	
Native American or Alaskan Native		0
Asian	43	
Black or African American	23	
Native Hawaiian or Other Pacific Islander		2
White	92	
Other	8	

9. Age group: 18-39 = 56  
40-59 = 79  
60 and over = 44

10. Los Angeles area: North = 61  
South = 26  
East = 23  
West = 68

11. Language spoken at home: Predominantly English,

I certify that the above information reflects all of the responses gathered at the August 12, 2002 meeting. No student, researcher, or doctors, RN's associated with the study filled out the forms.

The Stroke Trial Community Advisory Board. Members present were:  
Dr Geraldine Washington, President, NAACP Los Angeles Branch

Mr Milton Navarrate, National Association for the Hispanic Elderly, LA  
Mr. Robert Levy, Stroke Survivor  
Chaplain Pamela Lazor, Department of Spiritual Care, UCLA Medical Center  
Mr. Brian Studwell, Bel Air Association Board Member  
Mr Steve Lehrhoff, Director, Stroke Association of Southern California

We expect that we have met the requirements for the IRB to be able to provide us with the permission to proceed with Waiver. This is an on-going process and we will continue to work with the IRB for additional events and community programs. Please provide us with approval to proceed with Waiver effective after the IRB meeting.

If you have questions or concerns regarding this study, please feel free to contact me at 40594, or page me anytime (#11106).

Thank you much.

Sincerely,

Sidney Starkman, MD  
Clinical Professor  
Emergency Medicine and Neurology, UCLA  
Co-Director, UCLA Stroke Center

# UCLA Stroke Study Network

924 Westwood Boulevard, Suite 300  
Los Angeles, CA 90024  
310-794-0591 Fax 310-794-0599

**Fax**

Number of Pages

to Follow: *105*

*(14)*

Date: *August 13, 2002*

To: *Steve Peekman*

Fax: *49565*

From: Judy Guzy

Phone: (310) 794-0600

(310) 794-0599 FAX

Re: *IRB # 01-02-003*

Comments:

*list of phone calls  
& media community papers  
list for notification - as per  
media relations, these  
announcements are regularly  
placed.*

REDIFORM

REORDER NO. 50-17680-377

REDIFORM

REORDER NO. 50-17680-377

REDIFORM

P I O N E R M E M O R I S	TO	DATE	TIME	AM PM
	FROM	PHONE ( )		
	OF	CELL ( )		
		FAX ( )		
M E S S A G E	Confirming date & time for listing that was asked to her.			
	E-MAIL ADDRESS		SIGNED	
	PHONED <input type="checkbox"/>	CALL BACK <input type="checkbox"/>	RETURNED CALL <input type="checkbox"/>	WANTS TO SEE YOU <input type="checkbox"/>
	WAS IN <input type="checkbox"/>	URGENT <input type="checkbox"/>		

P I O N E R M E M O R I S	TO	DATE	TIME	AM PM
	FROM	PHONE (213) 262-5023		
	OF	CELL ( )		
		FAX (213) 580-1463		
M E S S A G E	American Heart Association Director of Public Advocacy			
	E-MAIL ADDRESS		SIGNED	
	PHONED <input type="checkbox"/>	CALL BACK <input type="checkbox"/>	RETURNED CALL <input type="checkbox"/>	WANTS TO SEE YOU <input type="checkbox"/>
	WAS IN <input type="checkbox"/>	URGENT <input type="checkbox"/>		

P I O N E R M E M O R I S	TO	DATE	TIME	AM PM
	FROM	PHONE (818) 718-6460		
	OF	CELL ( )		
		FAX ( )		
M E S S A G E	confirming directions will send e-mail for Dr. Starkman to confirm			
	E-MAIL ADDRESS		SIGNED	
	PHONED <input type="checkbox"/>	CALL BACK <input type="checkbox"/>	RETURNED CALL <input type="checkbox"/>	WANTS TO SEE YOU <input type="checkbox"/>
	WAS IN <input type="checkbox"/>	URGENT <input type="checkbox"/>		

P I O N E R M E M O R I S	TO	DATE	TIME	AM PM
	FROM	PHONE ( )		
	OF	CELL (310) 472-1942		
		FAX ( )		
M E S S A G E	stroke patient - will try to come - wanted specific directions - can't walk far			
	E-MAIL ADDRESS		SIGNED	
	PHONED <input type="checkbox"/>	CALL BACK <input type="checkbox"/>	RETURNED CALL <input type="checkbox"/>	WANTS TO SEE YOU <input type="checkbox"/>
	WAS IN <input type="checkbox"/>	URGENT <input type="checkbox"/>		



REDIFORM

REORDER NO. 50-17650-377

REDIFORM

REORDER NO. 50-17650-377

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PHONE MESSAGE

TO	8/7 12:00 PM
FROM	PHONE ( )
OF	CELL (213) 202-5006
	FAX ( )
MESSAGE	
E-MAIL ADDRESS	
PHONED <input type="checkbox"/>	CALL BACK <input type="checkbox"/>
RETURNED CALL <input type="checkbox"/>	WANTS TO SEE YOU <input type="checkbox"/>
WILL CALL AGAIN <input type="checkbox"/>	SIGNED
WAS IN <input type="checkbox"/>	URGENT <input type="checkbox"/>

PHONE MESSAGE

TO	DATE	TIME	AM
FROM	PHONE ( )	474-1613	PM
OF	CELL ( )		
	FAX ( )		
MESSAGE			
would like to come her husband may come too			
E-MAIL ADDRESS			
PHONED <input type="checkbox"/>	CALL BACK <input type="checkbox"/>	RETURNED CALL <input type="checkbox"/>	WANTS TO SEE YOU <input type="checkbox"/>
WILL CALL AGAIN <input type="checkbox"/>	WAS IN <input type="checkbox"/>	URGENT <input type="checkbox"/>	

PHONE MESSAGE

TO	DATE	TIME	AM
FROM	PHONE ( )	8/8	10:51 PM
OF	CELL ( )		
	FAX ( )		
MESSAGE			
would like further information on event & upcoming tarakhazer@yahoo.com stroke events			
2731 castle heights place			
LA 90034			
E-MAIL ADDRESS			
PHONED <input type="checkbox"/>	CALL BACK <input type="checkbox"/>	RETURNED CALL <input type="checkbox"/>	WANTS TO SEE YOU <input type="checkbox"/>
WILL CALL AGAIN <input type="checkbox"/>	WAS IN <input type="checkbox"/>	URGENT <input type="checkbox"/>	

PHONE MESSAGE

TO	DATE	TIME	AM
FROM	PHONE ( )	8/8	11:44 PM
OF	CELL ( )		
	FAX ( )		
MESSAGE			
Wanted directions to event. she will be attending			
E-MAIL ADDRESS			
PHONED <input type="checkbox"/>	CALL BACK <input type="checkbox"/>	RETURNED CALL <input type="checkbox"/>	WANTS TO SEE YOU <input type="checkbox"/>
WILL CALL AGAIN <input type="checkbox"/>	WAS IN <input type="checkbox"/>	URGENT <input type="checkbox"/>	

RECIFORM

REORDER NO. 90-17850-377

RECIFORM

REORDER NO. 90-178/50-377

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PHONE MESSAGE	TO	Masood Peze	DATE	8/8	TIME	12:41	AM	PM
	FROM		PHONE ( )					
	OF		CELL ( )					
			FAX ( )					
	Heard advertisement on Persian radio. Would like directions.							
	E-MAIL ADDRESS						SIGNED	
	PHONED <input type="checkbox"/>	CALL BACK <input type="checkbox"/>	RETURNED CALL <input type="checkbox"/>	WANTS TO SEE YOU <input type="checkbox"/>	WILL CALL AGAIN <input type="checkbox"/>	WAS IN <input type="checkbox"/>	URGENT <input type="checkbox"/>	

PHONE MESSAGE	TO	<i>to name</i>	DATE	8/8	TIME		AM	PM
	FROM		PHONE (310) 273-6639					
	OF		CELL ( )					
			FAX ( )					
	<i>return call 927-6263</i>							
	E-MAIL ADDRESS						SIGNED	
	PHONED <input type="checkbox"/>	CALL BACK <input type="checkbox"/>	RETURNED CALL <input type="checkbox"/>	WANTS TO SEE YOU <input type="checkbox"/>	WILL CALL AGAIN <input type="checkbox"/>	WAS IN <input type="checkbox"/>	URGENT <input type="checkbox"/>	

PHONE MESSAGE	TO	Vivian Haughton	DATE	8/8	TIME		AM	PM
	FROM		PHONE ( ) 446-					
	OF		CELL ( ) 1743					
			FAX ( )					
	<i>will try to make it</i>							
	E-MAIL ADDRESS						SIGNED	
	PHONED <input type="checkbox"/>	CALL BACK <input type="checkbox"/>	RETURNED CALL <input type="checkbox"/>	WANTS TO SEE YOU <input type="checkbox"/>	WILL CALL AGAIN <input type="checkbox"/>	WAS IN <input type="checkbox"/>	URGENT <input type="checkbox"/>	

PHONE MESSAGE	TO	Vielko Dusekberry	DATE	8/9	TIME		AM	PM
	FROM		PHONE (310) 231-9228					
	OF		CELL ( )					
			FAX ( )					
	<i>mother had a stroke - would like more info</i>							
	E-MAIL ADDRESS						SIGNED	
	PHONED <input type="checkbox"/>	CALL BACK <input type="checkbox"/>	RETURNED CALL <input type="checkbox"/>	WANTS TO SEE YOU <input type="checkbox"/>	WILL CALL AGAIN <input type="checkbox"/>	WAS IN <input type="checkbox"/>	URGENT <input type="checkbox"/>	

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 REORDER NO. 50-17680-377  
 REORDER NO. 50-17680-377  
 REFORM

<b>MESSAGE</b>	TO	<i>Lorris Cage</i>	DATE	<i>8/9/02</i>	TIME	AM PM
	FROM		PHONE ( )			
	OF		CELL ( <i>323850-1225</i> )			
			FAX ( )			
	MESSAGE <i>Theresa Terrace          Independent living          cant come tonight - wants          to make sure students          coming on 3rd</i>					
	E-MAIL ADDRESS				SIGNED	
	PHONED <input type="checkbox"/>	CALL BACK <input type="checkbox"/>	RETURNED CALL <input type="checkbox"/>	WANTS TO SEE YOU <input type="checkbox"/>	WILL CALL AGAIN <input type="checkbox"/>	WAS IN <input type="checkbox"/> URGENT <input type="checkbox"/>

<b>MESSAGE</b>	TO	<i>Cardice Howerton</i>	DATE	<i>8/1/02</i>	TIME	AM PM
	FROM		PHONE ( )			
	OF		CELL ( )			
			FAX ( )			
	MESSAGE <i>will come</i>					
	E-MAIL ADDRESS				SIGNED	
	PHONED <input type="checkbox"/>	CALL BACK <input type="checkbox"/>	RETURNED CALL <input type="checkbox"/>	WANTS TO SEE YOU <input type="checkbox"/>	WILL CALL AGAIN <input type="checkbox"/>	WAS IN <input type="checkbox"/> URGENT <input type="checkbox"/>

<b>MESSAGE</b>	TO		DATE		TIME	AM PM
	FROM		PHONE ( )			
	OF		CELL ( )			
			FAX ( )			
	MESSAGE (Empty)					
	E-MAIL ADDRESS				SIGNED	
	PHONED <input type="checkbox"/>	CALL BACK <input type="checkbox"/>	RETURNED CALL <input type="checkbox"/>	WANTS TO SEE YOU <input type="checkbox"/>	WILL CALL AGAIN <input type="checkbox"/>	WAS IN <input type="checkbox"/> URGENT <input type="checkbox"/>

<b>MESSAGE</b>	TO		DATE		TIME	AM PM
	FROM		PHONE ( )			
	OF		CELL ( )			
			FAX ( )			
	MESSAGE (Empty)					
	E-MAIL ADDRESS				SIGNED	

# Community papers list

Ruth Larsen  
Leisure World News  
P.O. Box 2338  
Seal Beach ,  
CA  
90740-1338

Attn: Diane Margolin  
Santa Monica Star  
1158 26th St., #614  
Santa Monica,  
CA  
90403

Anne Stubbs  
Senior Magazine  
3565 S. Higuera St.  
San Luis Obispo,  
CA  
93401-7394

Santa Monica Mirror  
P.O. Box 5877  
Santa Monica,  
CA  
90409-5877

March Schwartz  
Beverly Hills Courier  
8840 W. Olympic Blvd.  
Beverly Hills,  
CA  
90211

Editor  
Acton/Agua Dulce News  
P.O. Box 57  
Acton  
CA  
93510-0057

Editor  
San Fernando Sun  
601 S. Brand Ave.Ste. 202  
San Fernando,  
CA  
91340-4950

Editor  
Acorn  
30423 Canwood Street Suite 223  
Agoura Hills  
CA  
91301-4316

Art Aguilar  
Alhambra Post Advocate  
Wave Community Newspapers  
2621 West 54 Street  
Los Angeles,  
CA  
90043-2614

Russ Wiederspahn  
Arcadia Star  
1210 Azusa Canyon Road  
West Covina,  
CA  
91790-1003

Editor  
Arcadia Weekly, Monrovia Weekly,  
Pasadena Independent and Sierra Madre  
Weekly  
34 E. Huntington Drive  
Arcadia,  
CA  
91006

Editor  
Avalon Bay News  
P.O. Box 1809  
Avalon  
CA  
90704-1808

Editor  
Catalina Islander  
P.O. Box 428  
Avalon,  
CA  
90704-0428

Editor  
Azusa Herald  
1210 Azusa Canyon Road  
West Covina  
CA  
91790-1003

Editor  
Bell Gardens Sun  
2500 South Atlantic Blvd., Bldg B  
Los Angeles,  
CA  
90040-2004

Editor  
Burbank Leader  
220 North Glenoaks Blvd., Suite B  
Burbank  
CA  
91502-1213

Editor  
Burbank Times  
3917 Riverside Drive, 2nd Floor  
Burbank,  
CA  
91505-4327

Editor  
Carson Bulletin  
P.O. Box 4248  
Compton  
CA  
90224-4248

Editor  
Commerce Comet  
2500 South Atlantic Blvd., Bldg B  
Los Angeles,  
CA  
90040-2004

Editor  
Claremont Courier  
111 South College Avenue  
Claremont  
CA  
91711-5003

Editor  
The Californian  
P.O. Box 4248  
Compton,  
CA  
90224-4248

Editor  
Compton Bulletin  
P.O. Box 4248  
Compton  
CA  
90224-4248

Editor  
Highlander Covina Press Courier  
1210 Azusa Canyon Road  
West Covina,  
CA  
91790-1003

Brian Lewis  
Culver City Chronicle  
4201 Wilshire Blvd., Suite 600  
Los Angeles  
CA  
90010-3607

Editor  
Diamond Bar-Phillips Ranch  
Highlander  
1210 Azusa Canyon Road  
West Covina  
CA  
91790-1003

Editor  
Downey Eagle  
9047 Florence Avenue, Suite H  
Downey,  
CA  
90240-3400

Art Aguilar  
Downey Herald American  
Wave Community Newspapers  
2621 West 54 Street  
LA  
CA  
90043-2614

Editor  
Duarte Star  
1210 Azusa Canyon Road  
West Covina,  
CA  
91790-1003

Editor  
East Los Angeles Brooklyn  
Belevedere Comet  
2500 South Atlantic Blvd., Bldg B  
Los Angeles  
CA  
90040-2004

Editor  
El Segundo Herald  
P.O. Box 188  
El Segundo  
CA  
90245-0188

Editor  
Glendora Press  
1210 Azusa Canyon Road  
West Covina  
CA  
91790-1003

Editor  
Valley View  
601 S. Brand Blvd., #202  
San Fernando,  
CA  
91340-4950

Editor  
Hacienda Heights  
Highlander  
1210 Azusa Canyon Road  
West Covina  
CA  
91790-1003

Editor  
Easy Reader  
P.O. Box 427  
Hermosa Beach,  
CA  
90254-0427

Editor  
Highland Park News-Herald & Journal  
Wave Community Newspapers  
2621 West 54 Street  
Los Angeles  
CA  
90043-2614

Editor  
Inglewood Tribune  
P.O. Box 4248  
Compton,  
CA  
90224-4248

Editor  
San Fernando Sun  
1024 North Maclay St., Ste 9  
San Fernando  
CA  
91340-1361

Editor  
Desert Mailer News  
P.O. Box 4050  
Palmdale,  
CA  
93590-4050

Editor  
Bulletin & News  
P.O. Box 16045  
Long Beach  
CA  
90806-0545

Editor  
Downtown Gazette  
5225 East Second St.  
Long Beach  
CA  
90803-5326

Editor  
The Reporter  
P.O. Box 4278  
Long Beach  
CA  
90804-0278

Editor  
Belevedere Citizen  
Wave Community Newspapers  
2621 West 54 Street  
Los Angeles  
CA  
90043-2614

Editor  
Beverly Press  
P.O. Box 36036  
Los Angeles  
CA  
90036-0036

Editor  
City Terrace Comet  
2500 South Atlantic Blvd., Bldg B  
Los Angeles  
CA  
90040-2004

Editor  
Los Angeles Independent  
4201 Wilshire Blvd., Suite 600  
Los Angeles  
CA  
90010-3607

Editor  
Park LaBrea News  
P.O. Box 36036  
Los Angeles  
CA  
90036-0036

Editor  
Record Ledger  
1024 North Maclay Street., #9  
San Fernando  
CA  
91340-1361

Editor  
San Fernando Sun  
1024 North Maclay Street, Suite 9  
San Fernando  
CA  
91340-1361

Editor  
West Hollywood Independent  
4201 Wilshire Blvd., Suite 600  
Los Angeles  
CA  
90010-3607

Brian Lewis  
The Westsider  
4201 Wilshire Blvd., Suite 600  
Los Angeles  
CA  
90010-3607



Editor  
Wilshire Independent  
4201 Wilshire Blvd. , Ste 600  
Los Angeles  
CA  
90010-3607

Editor  
Lynwood Journal  
P.O. Box 4248  
Compton  
CA  
90224-4248

Editor  
Los Cerritos Community News  
P.O. Box 788  
Artesia  
CA  
90702-0788

Anne Soble  
Malibu Surfside News  
P.O. Box 903  
Malibu  
CA  
90265-0903

Editor  
The Malibu Times  
3864 Las Flores Canyon Road  
Malibu  
CA  
90265-5239

Editor  
Beach Reporter  
500 South Sepulveda Blvd., Ste 213  
Manhattan Beach  
CA  
90266-6983

Editor  
The Argonaut  
P.O. Box 11209  
Marina del Rey  
CA  
90295-7209

Editor  
The Foothill Leader  
111 W. Wilson Ave.  
Glendale,  
CA  
91203-2605

Editor  
American Eagle News  
18137 Parthenia Street  
Northridge  
CA  
91325-3301

Editor  
Southeast Cities Tribune  
P.O. Box 429  
Norwalk  
CA  
90651-0429

Editor  
Palisadian-Post  
P.O. Box 725  
Pacific Palisades  
CA  
90272-0725

Editor  
Palos Verdes Peninsula News  
P.O. Box 2609  
Palos Verdes Peninsula  
CA  
90274-8609

Editor  
Paramount Journal  
P.O. Box 2055  
Paramount  
CA  
90723-8055

Editor  
Pasadena Weekly  
Fifty South DeLacey Ave. Ste. 200  
Pasadena  
CA  
91105-1904

Geri Wilson  
San Marino Tribune  
2260 Huntington Drive  
San Marino  
CA  
91108-2688

Editor  
LaCanada Valley Sun  
P.O. Box 38  
La Canada, Flintridge  
CA  
91012-0038

Editor  
La Puente Highlander  
1210 Azusa Canyon Road  
West Covina,  
CA  
91790-1003

Editor  
South Pasadena Review  
P.O. Box 310  
South Pasadena  
CA  
91031-0310

Editor  
The Toluca Times  
10701 Riverside Drive  
Toluca Lake  
CA  
91602

Health Watch  
Health  
Los Angeles Times  
202 W. 1st Street  
Los Angeles,  
CA,  
90012

Editor  
Beverly Hills (213)  
9777 Wilshire Blvd., Ste 707  
Beverly Hills  
CA  
90212-1907

Editor  
#Bmrtwd  
2118 Wilshire Blvd., Suite 1060  
Santa Monica  
CA  
90403-5784

Editor  
Senior Living Magazine  
P.O. Box 2065  
Glendale  
CA  
91209-2065

Editor  
So. Calif. Senior Life  
6022 West Pico Blvd. , Ste 7  
Los Angeles  
CA  
90035-2625

Editor  
Inglewood Tribune  
P.O. Box 4248  
Compton,  
CA  
90224-4248

~~Involvement/Opportunities  
Life & Style  
LA Times  
Times Mirror Square  
LA  
CA  
90053~~

~~Volunteer Calendar  
Daily News  
21221 Oxnard St.  
Woodland Hills  
CA  
91367-5081~~

~~Richard Howland  
AHelping Others@  
Press-Telegram  
604 Pine Avenue  
Long Beach  
CA  
90844/0003~~

~~Volunteer Opportunities  
Pasadena Star-News  
911 East Colorado Blvd.  
Pasadena  
CA  
91109-1700~~

~~Leila Badalian  
Brentwood Media Group  
P.O. Box 49264  
LA  
CA  
90049~~

Alice McCracken,  
Associate Editor  
California Seniors  
1000 Pioneer Way  
El Cajon,  
CA  
92020

# UCLA Stroke Study Network

Westwood Boulevard, Suite 300  
Los Angeles, CA 90024  
310-794-0591 Fax 310-794-0599

**Fax**

Number of Pages  
to Follow: 2

Date: 8/13/02

To: Steve Peckman

Fax: 49565

From: Sidney Starkman, MD  
[starkman@ucla.edu](mailto:starkman@ucla.edu)

Phone: (310) 794-0594  
(310) 794-0599 FAX

Re: Notifications IRB # 01-02-003

Comments:

Additional community agencies we notified through  
flyer mailings.

\*\*\*\*\*  
 \* ACTIVITY REPORT \*  
 \*\*\*\*\*

NAME:  
 TEL :  
 DATE:08/13/02 17:24

TYPE	SESS	DEPT	DATE/TIME	DURATION	REMOTE ID	SPEED	PAGE	RESULT
AUTO RX	783		08-08 16:09	00'45		144	01	OK -0000
AUTO RX	784		08-08 19:07	01'30	PUREFAX IO 4380 CH3	144	02	OK -0000
AUTO RX	785		08-09 06:24	01'09		E- 144	03	OK -0000
AUTO RX	786		08-09 08:03	00'39	301 309 8470	E- 144	01	OK -0000
MEMORY TX	787		08-09 09:39	00'40	Wellpoint	144	02	OK -0000
MEMORY TX	788		08-09 11:43	00'55	310 794 9747	E- 144	01	OK -7900
AUTO RX	789		08-09 11:52	01'09	301 480 1080	E- 144	03	OK -0000
AUTO RX	790		08-09 12:06	00'50	12	144	01	OK -0000
DIRECT TX	791		08-09 12:43	01'25	310 267 2063	E- 144	04	OK -36c0
DIRECT TX	792		08-09 12:47	01'29	310 7943313	E- 144	04	OK -7900
AUTO RX	793		08-09 13:23	00'33	9858757547	E- 144	01	OK -0000
AUTO RX	794		08-09 17:16	01'00	Association Center	144	02	OK -0000
AUTO RX	795		08-09 17:18	01'00	Association Center	144	02	OK -0000
AUTO RX	796		08-10 16:16	00'53		144	01	OK -0000
AUTO RX	797		08-11 11:06	00'41	Via Fax	E- 144	01	OK -0000
AUTO RX	798		08-11 12:55	00'51		144	02	OK -0000
AUTO RX	799		08-12 09:27	00'50	310 782 1763	E- 144	01	OK -0000
AUTO RX	800		08-12 09:40	00'31		E- 144	01	OK -0000
AUTO RX	801		08-12 10:11	00'42	(877) 8275658	E- 144	01	OK -0000
MEMORY TX	803		08-12 14:58	00'43	310 206 5239	E- 144	02	OK -36c0
AUTO RX	804		08-12 15:16	00'51	562 431 3947	E- 144	02	OK -0000
MEMORY TX	802		08-12 15:32	01'27	2065239	E-	00	NO ANSWER -0000
AUTO RX	805		08-12 17:27	00'47		144	01	OK -0000
AUTO RX	806		08-12 20:09	00'57		144	01	OK -0000
AUTO RX	807		08-12 23:02	01'30		96	01	OK -0000
AUTO RX	808		08-13 07:20	00'57	Born & Bicknell, Inc	E- 144	02	OK -0000
AUTO RX	809		08-13 09:17	07'55	310 267 2063	E- 144	06	OK -0000
MEMORY TX	810		08-13 09:57	01'00	310 794 9747	E- 144	01	OK -7900
MANUAL TX	811		08-13 10:19	00'51	3107949272	E- 96	02	OK -5655
AUTO RX	812		08-13 10:51	00'51	310 206 0063	E- 144	02	OK -0000
AUTO RX	813		08-13 11:49	06'34	8026569337	E- 120	09	OK -0000
AUTO RX	814		08-13 13:50	01'11		E- 144	02	OK -0000
AUTO RX	815		08-13 15:01	00'35		E- 144	01	OK -0000
AUTO RX	816		08-13 15:46	00'46		144	01	OK -0000
DIRECT TX	817		08-13 17:01	03'55	3107949565	E- 144	14	OK -1915
MANUAL TX	818		08-13 17:23	00'58	3107949565	E- 144	03	OK -1915

03/26 1996 V1.7A  
 TOTAL TX=192411 TOTAL RX=262380

## Community Agency List for Stroke Flyer

- ✓ Devin Wallace  
Stroke Association  
2001 S. Barrington #308  
Los Angeles, CA 90025
- ✓ Donna Benton  
Los Angeles Caregiver Resource Center  
3715 McClintock Ave.  
Los Angeles, CA 90089-0191
- ✓ Estee Bienstock  
Allpoint Home health  
10700 Santa Monica Blvd. Suite 10  
Los Angeles, CA 90025
- ✓ Rosalie Gotz  
Culver City Senior Center  
4153 Overland Ave.  
Culver City, CA 90230-3733
- ✓ Susan Pomerantz  
Concepts for Living  
6351 Owensmouth Ave. #202  
Woodland Hills, CA 913677
- ✓ Julie Steres  
Center for Healthy Aging  
1527 4<sup>th</sup> Street  
Santa Monica, CA 90401
- ✓ Holly Kiger  
Center for Healthy Aging  
2125 Arizona Ave.  
Santa Monica, CA 90404-1337
- ✓ Didi Hirsch Community Mental Health  
Center  
Older Adult Services  
4760 S. Sepulveda Blvd.  
Culver City, CA 90230-4888
- ✓ Maggie Hall  
Emeritus College  
1443 2<sup>nd</sup> Street  
Santa Monica, CA 90401
- ✓ Irene Wechsler  
Elderlink  
P.O.Box 5202  
Santa Monica, CA 90409
- ✓ Mary Jo Dalton  
First United Methodist Church  
1008 11<sup>th</sup> Street  
Santa Monica, CA 90403
- ✓ Evelyn Mandel  
Gerontology Home Companion  
1427 7<sup>th</sup> Street. Suite 3  
Santa Monica, CA 90401
- ✓ Brad Lusk  
Home Instead Senior Care  
2001 S. Barrington Ave. Suite 209  
Los Angeles, CA 90025
- ✓ Linda Laisure  
H.O.M.E.  
1020 Rose Avenue  
Venice, CA 90291
- ( Steve Barlam  
LivHOME  
5900 Wilshire Blvd. Suite 705  
Los Angeles, CA 90036 ) *repeat*
- ✓ Anita Miller  
Law Offices of Mitchell Karasov  
12650 Riverside Dr.  
North Hollywood, CA 91607
- ✓ Terry Magady  
The Elderlaw Center  
11400 W. Olympic Blvd.  
Ninth Floor  
Los Angeles, CA 90064-1557

- ✓ Luanne Tessier  
Senior Outreach  
St. Joseph's Center  
204 Hampton Dr.  
Venice, CA 90291-8633
- ✓ Liz Wilson  
WISE Senior Services  
1527 4<sup>th</sup> Street  
Santa Monica, CA 90401
- ✓ Kathy LePrevost  
City of Santa Monica  
Senior Services  
1527 4<sup>th</sup> Street  
Santa Monica, CA 90401
- ✓ Victoria Neal  
OASIS  
Robinsons-May/Westside Pavilion  
10730 W. Pico Bld.  
3<sup>rd</sup> Floor  
Los Angeles, CA 90064
- ✓ OPICA Adult Day Care Center  
11759 Missouri Ave.  
Los Angeles, CA 90025
- ✓ Sue Hartenbaum  
Long-Term Care Insurance  
15332 Antioch St. #160  
Pacific Palisades, CA 90272
- ✓ Anita Ybarra  
City of Santa Monica  
Senior Services  
1527 4<sup>th</sup> Street  
Santa Monica, CA 90401
- ✓ Phyllis Keefer  
TLC Program  
Saint John's Health Center  
1328 22<sup>nd</sup> Street  
Santa Monica, CA 90404-2091
- ✓ Leslie McDougall  
Westside Center for Independent Living  
12901 Venice Blvd.  
Los Angeles, CA 90066
- ✓ Marlene Singer  
Jewish Family Services of Santa Monica  
1424 4<sup>th</sup> Street. Suite 303  
Santa Monica, CA 90401
- ✓ Felicia Mahood Senior Center  
11338 Santa Monica Blvd.  
Los Angeles, CA 90025
- ✓ Freda Mohr Multipurpose Senior Center  
330 N. Fairfax Ave.  
Los Angeles, CA 90036
- ✓ Roxbury Park Community Center  
471 S. Roxbury Dr.  
Beverly Hills, cA 90212
- ✓ The Salvation Army  
1533 4<sup>th</sup> Street  
Santa Monica, CA 90401
- ✓ Older Adult Services  
Santa Monica Family YMCA  
1332 6<sup>th</sup> Street  
Santa Monica, CA 90404
- ✓ Israel Levin Senior Adult Center  
201 Ocean Front Walk  
Venice, CA 90291



# **UCLA** Stroke Study Network

924 Westwood Boulevard, Suite 300  
Los Angeles, CA 90024  
310-794-0591 Fax 310-794-0599

August 26, 2002

Robert Figlin, MD, Chairperson  
Office for Protection of Research Subjects  
Medical Institutional Review Board 2  
2107 Ueberroth Building  
Campus Mail Code 169407

RE: **Request for Additional Information Prior to Determination on  
Waiver of Informed Consent**  
UCLA IRB #01-02-003-02A  
Mechanical Embolus Removal in Cerebral Ischemia (MERCİ) (Modifications requested  
per MIRB letter of August 15, 2002)

Dear Dr. Figlin:

**Please see our answers to the committee correspondence of 8-15-02 in bold.**

1. Your report requests that the August 12 community meeting serve as the first meeting of the Stroke Trial Community Advisory Board. The MIRB highlighted the importance of the Advisory Board in your proposal and expressed concern that the Advisory Board has not had an independent meeting to discuss and opine, as a group or individually, on the proposed research and the possibility of the waiver as provided in your July 10 plan. The MIRB Sub-Committee (SC) asked and you agreed during the July 18, 2002 meeting that the Advisory Board would be provided a copy of the research informed consent form to review as surrogates for potential subjects within their constituencies. Additionally, the SC requested and you agreed and notified the IRB that you would inform the SC in advance of meetings of the Advisory Board to allow attendance of the SC members or their representatives. Therefore, the MIRB did not approve the August 12 community meeting as the definitive meeting of the Advisory Board sufficient to complete the initial consultation and approve the waiver.

The MIRB will be happy to receive and review as soon as possible your response to the following items in order to determine whether to grant the waiver of informed consent:

Your August 13, 2002 report indicates the Advisory Board members present at the August 12 meeting were Dr. Geraldine Washington, Mr. Milton Navarette, Mr. Robert Levey, Chaplain Pamela Lazor, Mr. Brian Studwell, and Mr. Steve Lehrhoff. Your July 10, 2002 response indicated a representative from the Los Angeles office of the American Association of Retired Persons (AARP) is also a member of the Advisory Board. Please clarify whether the selected AARP representative continues as a member of the Advisory Board. Additionally, please identify the AARP representative.

**Mr. David Damian Figueroa of the AARP has agreed to serve as a member of the Advisory Board. Mr. Figueroa is the Assoc Director, AARP California**

2. Please provide the name of the Chair of the Advisory Board.

**Steven Lehrhoff, Director of the Stroke Association of Southern California will Chair the Advisory Board.**

3. The MIRB requests, consistent with your Advisory Plan of July 10, 2002, the agreement of July 18, and the subsequent letter of July 22, 2002, that the Advisory Board meet and discuss the research, the consent document, and the waiver of informed consent and provide the MIRB with a letter indicating their position on the waiver of informed consent. If they are not unanimous in their decision, the MIRB asks that they forward any minority opinions for review. Additionally, as indicated in your July 10 plan, the Advisory Board members should consult with their communities regarding the research and provide a report to the IRB of these meetings and their findings.

**We assure the Committee that the Advisory Board will meet and discuss the research, the consent document, and the waiver of informed consent. The Stroke Trial Advisory Board will be meeting on the evening of September 5<sup>th</sup> at 7 PM. We can expect a letter from the Advisory Board to the IRB indicating their position on the waiver of informed consent. If not unanimous in their decision, we expect the letter will address any minority opinions. The letter will be submitted to the IRB for review. As indicated in the July 10 plan, "Board members will be asked to consult with their communities regarding the study." The plan did not include Advisory Board members' holding formal meetings with their respective communities nor the Advisory Board members providing detailed, formal reports to the IRB of such meetings. The members of the Advisory Board were selected because they each bring a special perspective on the subject of Waiver of Consent and it's applicability to acute stroke research at UCLA. We expect members of the Advisory Board to be responsible in being a representative of their respective communities based on personal experience, past broad interactions and knowledge of their communities, and informal continuing consultations with their communities.**

4. Please assure the MIRB that the Advisory Board will have sufficient time and facilities to meet independently of the research team.

**We assure the MIRB that the Advisory Board will have sufficient time and facilities to meet independently of the research team**

5. The MIRB requests, consistent with the SC recommendations, that members of the SC or their representatives attend the Advisory Board meeting and provide information regarding the waiver requirements.

**We assure the MIRB that members of the SC or their representatives are invited to attend the Advisory Board meeting and provide information regarding the waiver requirements**

Additionally, the MIRB requests that you provide information about the following aspects of the protocol:

During the August 12 meeting you indicated that study investigators would attempt to obtain assent from family members and will recognize the dissent of family members, per 21 CFR

50.24(b). Please outline (a) the process for identifying family members, (b) the amount of time available to identify and discuss the research with such a person and still effectively enroll the subject in the research, and (c) how you will document the process of attempts to identify family members and obtaining their assent.

- a) **The process for identifying family members: If family members or legally authorized representatives (LARs) names and telephone numbers are known when the patient presents, diligent efforts will be made to reach the next of kin or LAR, in order of power of attorney, health care conservatorship, spouse, adult child, parent, sibling. Attempts to contact these individuals will be repeated prior to initiating waiver of consent. If patient arrives without known family members or LARs names, there will be multiple attempts to contact one, calling all available telephone numbers found in the patient's belongings, medical records, primary physicians if known, or by using directory assistance. When possible, we will request that a LA City or respective LA County jurisdiction police officer go to the patient's address if known to attempt to locate family. The social worker on call for the Emergency Department will be requested to assist the study investigators and research coordinators in their efforts.**
- b) **The amount of time available to identify and discuss the research with such a person and still effectively enroll the subject in the research is theoretically up to the maximum permitted in the research trial. In the MERCI trial, time to initiating Clot Retrieval must be within 8 hours of stroke onset. However more brain is dying every minute that is spent trying to track down family members or LARs. Making a patient ready for treatment at thirty minutes post onset wait another 7.49 hours before treatment is started because no family or LAR is initially reached imperils the patient and the ability of the trial to detect a treatment effect. After we have exhausted the above, and at least thirty minutes has transpired, the patient will be enrolled utilizing Waiver. If next of kin or LAR cannot be reached for assent after thirty minutes of concerted effort, enrollment will not be delayed. Accordingly, we propose that up to a maximum of 30 minutes be spent trying to identify and reach family member or LAR. Once reached, discussion of the research with the family member or LAR will continue for as long as is required to have all issues in the informed consent addressed and all questions answered. The informed consent will be used as a template for obtaining assent to proceed with waiver.**
- c) **Documentation will be made documenting time, date, name, and telephone number of attempted contacts. When contact is made, the date, time, name of contact, and relationship will be documented in the chart. A note will be made regarding obtaining the contact's assent. Objection to enrollment will also be noted in the chart and a note indicating that patient was not enrolled because of objection and by whom.**

Should you have any concerns or require additional information, please feel free to contact me directly at 40594 or pager #11106.

Sincerely,

Sidney Starkman, MD  
Clinical Professor  
Emergency Medicine and Neurology, UCLA  
Co-Director, UCLA Stroke Center

# **UCLA** Stroke Study Network

924 Westwood Boulevard, Suite 300  
Los Angeles, CA 90024  
310-794-0591 Fax 310-794-0599

October 2, 2002

Robert Figlin, MD, Chairperson  
Office for Protection of Research Subjects  
Medical Institutional Review Board 2  
2107 Ueberroth Building  
Campus Mail Code 169407

RE: Request to Provide for Additional Information Prior to Issuing An Approval Notice  
UCLA IRB #01-02-003-02A IRB Correspondence of September 3, 2002  
Mechanical Embolus Removal in Cerebral Ischemia (MERCİ)

Dear Dr. Figlin,

So that this letter will be easier to read and follow, items in **bold** are extracted from Committee Correspondence.

**September 3, 2002,**

**1. Thank you for notifying the Board of the Advisory Board meeting scheduled for September 5, 2002. As requested by the MIRB in our previous correspondence, members of the MIRB Sub-Committee (SC) will also be attendance at that meeting."**

The September 5 meeting needed to be cancelled. We learned at the last minute that two Advisory Board members would not be able to attend. We contacted Steven Peckman immediately and he consulted with the IRB Committee Chairs (or acting chairs). Steven Peckman informed us that an Advisory Board meeting with six out of seven board members would have been acceptable, however, five out of seven would not have been sufficient. Fortunately we were able to reach everyone in time and cancel the September 5<sup>th</sup> meeting. The Advisory Board meeting was rescheduled for September 23 and is described below. Both Steve Peckman and John Fraser (MIRB Vice-Chair) attended the September 23 meeting.

**2. The Committee looks forward to the Advisory Board's correspondence regarding their position on the study and the proposed waiver of informed consent. As indicated in previous correspondences, the report should include any minority opinions expressed during the meeting.**

The Advisory Board's correspondence regarding their position on the study and the proposed waiver of informed consent is enclosed. Their position is unanimous.

We understand the MIRB's not approving the August 12 community meeting as the definitive meeting of the Advisory Board sufficient to complete the initial consultation and approve the waiver. We are now delighted to report that we have held a definitive meeting of the Advisory Board.

The Advisory Board consists of six members plus the AARP California representative, Mr. David Damian Figueroa, State Associate Director. Despite numerous communications with Mr. Figueroa, including e-mails, which indicated his desire to participate and attend the Advisory Board meetings, he informed us late on September 5 that he could not be part of the Advisory Board. We forwarded Mr. Damian's prior enthusiastic e-mails to Mr. Steven Peckman. We proceeded with a six out of seven member Advisory Board as per our understanding as to the minimal requirement at the time of canceling the Advisory Board meeting on September 5, while continuing to solicit additional representation from the AARP or a replacement before the definitive Advisory Board meeting.

The Stroke Trials Community Advisory Board Meeting was held September 23rd at 7pm. In attendance were: Dr Geraldine Washington, President, NAACP, Los Angeles Branch, Mr. Melvin Navarrete, representing Dr Carmela Lacayo, Director, National Association for Hispanic Elderly (who herself was unable to attend at the last minute), Mr. Brian Studwell, Bel-Air Association Board Member, Mr. Robert Levy, Stroke Survivor, and Mr. Steven Lehrhoff, President, Stroke Association of Southern California. Representing the UCLA IRB committee were Mr. Steve Peckman, and Dr John Fraser. Members of the UCLA Stroke Team present were Dr Jeffrey Saver, Dr Sidney Starkman and Judy Guzy, RN.

At the 2+hour meeting, the investigators reviewed again details of the trial with the members of the Stroke Trials Community Advisory Board, Mr. Peckman, and Dr. Fraser. The investigators then left the conference room and Mr. Peckman and Dr. Fraser held further discussions with the Board. The Stroke Trials Community Advisory Board then discussed the trial alone in closed session, independently. All 5 full-fledged board members present unanimously endorsed the emergency waiver. Dr. Lacayo, represented at the meeting by Mr. Navarrete, also endorsed the emergency waiver, after consulting with Mr. Navarrete after the meeting, yielding a final Advisory Board vote of 6-0 in favor of waiver of consent. The Chair of the Advisory Board, Mr. Steve Lehrhoff, spoke with Dr Lacayo directly to confirm her endorsement. Enclosed is the letter written by the Chair of the Stroke Trials Community Advisory Board, individually signed by each committee member endorsing emergency waiver.

In discussions with Steven Peckman, we understand that there may have been an outstanding "action item" that would preclude the IRBs providing permission to proceed with waiver. We understand that there may have been concern by the Committee that despite the large turn out at the Community Meeting of August 12, 2002, the Hispanic community needed additional input. Accordingly, on September 24, 2002, Dr Starkman arranged for a meeting of the National Association of Hispanic Elderly, Los Angeles. During the 2-hour meeting, there was a presentation of the MERCI trial and emergency waiver.

The audience was primarily Hispanic and elderly. Enclosed are the 192 forms, in English and Spanish, collected from approximately 205 attendees. A summary of their responses follows as well as copies of the completed forms. The results have been entered in a database which is attached. A "B=Blank" in the total indicates that the item was left blank or there were more than one response. We wish to assure the Committee that this is a true reflection of the community's response to waiver, which replicates what transpired at the Community Meeting of August 12, and witnessed by UCLA IRB staff and members.

We feel that the program was enormously successful in communicating and consulting with the Hispanic Community in addition to the August 12 community meeting, and the survey demonstrates an overwhelming majority approval of the waiver. The response to question number five, though still a high percentage, reflects the communities wishes to be able to give consent themselves or for their family members, similar to what we learned on the August 12 Community meeting. The response to question #6 demonstrates the communities overwhelming wish to have this research proceed.

On September 13, as soon as we confirmed the National Association of Hispanic Elderly meeting for September 24th, we communicated with Steven Peckman regarding the event. Despite our best efforts to assist Steven Peckman's or other IRB staff or committee Member's attendance, for even part of the meeting, we understand that Steven Peckman was unable to attend himself and was unsuccessful in obtaining another IRB representative.

Total Number of Surveys Completed: 192

1. Has the study been explained so that you understand the risks and possible benefits of the stroke treatment?  
Yes 184 (96%)  
No 5 (3%)  
Blank 3 (2%)
2. Do you understand that patients will be enrolled without their consent, or the consent of a family member, at least initially?  
Yes 171 (89%)  
No 14 (7%)  
Blank 7 (4%)
3. Do you understand that patients will be treated and if family or legally authorized representative is reached, they will have an opportunity to withdraw the patient from the research or approve continued participation?  
Yes 170 (88%)  
No 17 (9%)  
Blank 5 (3%)
4. Was it made clear that all patients will receive the standard care for acute stroke, whether or not they take part in this research study?  
Yes 180 (94%)

No 6 (3%)  
Blank 6 (3%)

5. Would you be willing to participate in this study or have a family member participate without your consent?

Yes 159 (83%)  
No 28 (15%)  
Blank 5 (3%)

6. In view of what you have learned here, are you willing for this study to be done in your community?

Yes 159 (83%)  
No 29 (15%)  
Blank 3 (2%)

7. If you answer no to either #5 or #6, please tell us what changes you would suggest. There was only one response to this question, which was un-interpretable.

8. Ethnicity:

Hispanic or Latino	175 (91%)	
Not Hispanic or Latino		
Native American or Alaskan Native		4 (2%)
Asian	5 (3%)	
Black or African American	4 (3%)	
Native Hawaiian or Other Pacific Islander		0
White	4 (3%)	
Other		

9. Age group: 18-39 = 1 (0.5%)  
40-59 = 50 (26%)  
60 and over = 136 (71%)

10. Los Angeles area: North = 24 (13%)  
South = 42 (22%)  
East = 73 (38%)  
West = 45 (23%)

11. Language spoken at home: Predominantly Spanish

We expect that we have met the requirements for the IRB to be able to provide us with the permission to proceed with Waiver in the MERCI trial.

If you have questions or concerns regarding this study, please feel free to contact me at 40594, or page me anytime (#11106).

Thank you much.

Sincerely,

A handwritten signature in black ink that reads "Sidney Starkman MD". The signature is written in a cursive style with a clear "MD" at the end.

Sidney Starkman, MD  
Clinical Professor  
Emergency Medicine and Neurology, UCLA  
Co-Director, UCLA Stroke Center

Enclosures

1. Stroke Trials Committee Advisory Board Letter with signatures
2. Surveys from the National Association of Hispanic Elderly





**Stroke Association  
of Southern California**

**September 24, 2002**

**Robert Figlin, MD, Chairperson  
Office for Protection of Research Subjects  
Medical Institutional Review Board 2  
2107 Usberroth Building  
Campus Mail Code 169407**

**RE: UCLA IRB #01-02-003-02C  
Mechanical Embolus Removal in Cerebral Ischemia (MERCİ)**

**The UCLA Stroke Trial Community Advisory Board has reviewed the MERCİ Study.  
The members of the Advisory Board are:**

**Mr. Steven Lehrhoff  
Director, Stroke Association of Southern California**

**Chaplain Pamela Lazor  
Department of Spiritual Care, UCLA Medical Center**

**Mr. Robert Levy  
Stroke Survivor**

**Dr. Carmela Lacayo, Director of the National Association for Hispanic Elderly  
(Asociación Nacional Por Personas Mayores) was represented by Mr. Milton Navarrete**

**Dr. Geraldine R. Washington  
President  
NAACP, Los Angeles Branch**

**Mr. Brian Studwell  
Bel Air Association Board Member**

**All the above attended the Town Hall Community Meeting held on August 12, 2002, and met again with the investigators and in closed session without the investigators for final review of the MERCİ study and protocol on September 23, 2002. They received a detailed presentation at these meetings and were provided copies of relevant documents for their review in advance. Mr. Steven Peckman and Dr. John Frazer participated in the meeting of the Advisory Board.**

**As representatives of their respective communities they fully endorse proceeding with the emergency waiver. The Advisory Board will be apprised whenever a patient is enrolled under the Waiver provision and will be immediately informed of any serious adverse**

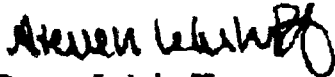
Page 2  
UCLA IRB #01-02-003-02C

event. They will also be provided an anonymous summary of all patients in the study and will continue to be apprised of any new information as it is obtained.

On September 23, 2002, The Stroke Trial Community Advisory Board members in a vote unanimously endorsed the use of waiver of explicit consent for research in emergency circumstances for the MERCI Study. Mr. Navarrete provided input and discussion at the meeting but abstained from the voting as that responsibility belonged to Dr. Lacayo. Following Mr. Navarrete's report to Dr. Lacayo, I spoke with her and confirmed her endorsement.

We wish to inform the UCLA IRB that the UCLA Stroke Trial Community Advisory Board, with due diligence, unanimously endorse the emergency waiver.

Sincerely,



Steven Lehrhoff  
Chair, UCLA Stroke Community Advisory Board



Steven Lehrhoff, Director, Stroke Association of Southern California

Chaplain Pamela Lazor, Department of Spiritual Care, UCLA Medical Center

Dr. Geraldine R. Washington, President, NAACP, Los Angeles Branch



Dr. Carmela Lacayo, Director of the National Association for Hispanic Elderly (Asociación Nacional Por Personas Mayores), Los Angeles

Mr. Brian Studwell, Bel Air Association Board Member

Mr. Robert Levy, Stroke Survivor

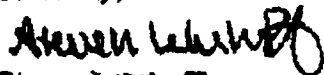
Page 2  
UCLA IRB #01-02-003-02C

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We wish to inform the UCLA IRB that the UCLA Stroke Trial Community Advisory Board, with due diligence, unanimously endorse the emergency waiver.

Sincerely,



Steven Lehrhoff  
Chair, UCLA Stroke Community Advisory Board

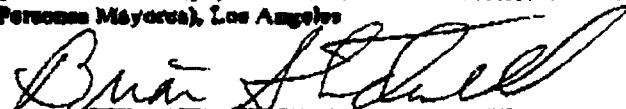


Steven Lehrhoff, Director, Stroke Association of Southern California

Chaplain Pamela Lazar, Department of Spiritual Care, UCLA Medical Center

Dr. Geraldine R. Washington, President, NAACP, Los Angeles Branch

Dr. Carmela Lacayo, Director of the National Association for Hispanic Elderly (Asociación Nacional Por Personas Mayores), Los Angeles



Mr. Brian Studwell, Bel Air Association Board Member

Mr. Robert Levy, Stroke Survivor

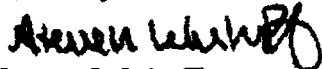
Page 2  
UCLA IRB #01-02-003-02C

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On September 23, 2002, The Stroke Trial Community Advisory Board members in a vote unanimously endorsed the use of waiver of explicit consent for research in emergency circumstances for the MERCI Study. Mr. Navarrete provided input and discussion at the meeting but abstained from the voting as that responsibility belonged to Dr. Lacayo. Following Mr. Navarrete's report to Dr. Lacayo, I spoke with her and confirmed her endorsement.

We wish to inform the UCLA IRB that the UCLA Stroke Trial Community Advisory Board, with due diligence, unanimously endorse the emergency waiver.

Sincerely,



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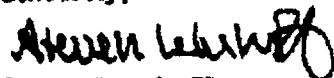
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**MERCI STROKE TRIALS COMMUNITY  
CONSULTATION**

**NATIONAL ASSOCIATION OF  
HISPANIC ELDERLY**

**SEPTEMBER 23, 2002**

#	Q1	Q2	Q3	Q4	Q5	Q6	Q7 Comments	Ethnicity	Age 18-39	Age 40-59	Age 60 +	Home Area	Language Spoken
1	Y	Y	Y	Y	Y	Y		H			X	N	S
2	Y	Y	Y	Y	Y	Y		H			X	W	S
3	Y	Y	N	N	Y	Y		H			X	N	S
4	Y	Y	Y	Y	Y	Y		H			X	W	S
5	Y	Y	Y	Y	Y	Y		H			X	W	S
6	Y	Y	Y	Y	Y	Y		H			X	B	S
7	Y	Y	Y	Y	Y	Y		H			X	B	B
8	Y	Y	Y	N	Y	Y		H			X	E	B
9	Y	Y	Y	Y	Y	Y		H			X	E	S
10	Y	Y	Y	Y	Y	Y		H			X	E	S
11	N	Y	Y	Y	N	Y		H			X	E	S
12	Y	Y	Y	Y	Y	Y		H			X	W	S, E
13	Y	Y	Y	Y	Y	Y		H			X	S	S
14	Y	Y	Y	Y	Y	Y		H		X		S	S
15	Y	Y	Y	Y	Y	Y		H			X	N	S
16	Y	Y	Y	Y	Y	Y		H			X	N	S
17	Y	Y	Y	Y	Y	Y		H			X	S	S
18	Y	Y	Y	Y	Y	Y		H			X	N	S
19	Y	B	Y	Y	Y	Y		H			X	S	S
20	Y	Y	Y	Y	Y	Y		H			X	W	S
21	Y	Y	Y	Y	Y	Y		H			X	S	S
22	Y	Y	Y	Y	Y	Y		H			X	N	S, E
23	Y	Y	Y	Y	Y	Y		H			X	E	S
24	Y	Y	Y	Y	Y	Y		H			X	E	S
25	Y	Y	Y	Y	Y	Y		H, W			X	S	S
26	Y	Y	Y	Y	Y	Y		H			X	S	S
27	Y	Y	Y	Y	Y	Y		H			X	S	S
28	Y	N	N	Y	Y	Y		H			X	W	S
29	Y	Y	Y	Y	N	Y		H, O		X		N	S
30	Y	Y	Y	Y	Y	Y		H			X	E	S
31	Y	Y	Y	Y	Y	Y		H		X		E	S
32	Y	Y	Y	Y	Y	Y		H			X	E	S
33	Y	Y	N	Y	Y	Y		H			X	N	S
34	Y	Y	Y	Y	Y	Y		H, W		X		S	S
35	Y	Y	Y	Y	Y	Y		H		X		S	S
36	Y	Y	Y	Y	Y	Y		H			X	E	S
37	Y	Y	Y	Y	Y	Y		H, W			X	W	S
38	Y	Y	Y	Y	Y	Y		H, W			X	W	S
39	Y	Y	Y	Y	Y	Y		H			X	W	S
40	Y	Y	B	Y	Y	Y		H		X		S	S
41	Y	Y	Y	Y	Y	Y		B			X	E	S
42	Y	Y	Y	Y	Y	Y		H			X	E	S
43	Y	Y	Y	Y	Y	Y		H			X	S	S
44	Y	Y	Y	Y	Y	Y		H			X	N	S



#	Q1	Q2	Q3	Q4	Q5	Q6	Q7 Comments	Ethnicity	Age 18-39	Age 40-59	Age 60 +	Home Area	Language Spoken
45	Y	Y	Y	Y	Y	Y		H			X	N	S, E
46	N	Y	Y	B	Y	Y		B		X		S	S
47	Y	N	Y	Y	Y	Y		H			X	S, W	S
48	Y	N	Y	Y	N	Y		H		X		E	S
49	Y	N	N	Y	Y	Y		H			X	W	S
50	Y	Y	N	Y	Y	Y		H		X		B	S
51	Y	Y	Y	Y	Y	Y		H		X		W	S
52	Y	Y	Y	Y	Y	Y		H			X	E	B
53	Y	Y	B	B	B	Y		H			X	E	B
54	Y	Y	N	Y	Y	Y		H			X	E	B
55	Y	Y	Y	Y	Y	Y		H			X	S	S
56	Y	Y	Y	Y	Y	Y		H			X	W	S
57	Y	Y	Y	Y	Y	Y		H			X	S	S, E
58	Y	Y	Y	Y	Y	Y		H		X		B	B
59	Y	Y	Y	Y	Y	Y		H		X		W	S
60	Y	Y	Y	Y	Y	Y		H		X		E	S
61	Y	Y	Y	Y	Y	Y		H		X		E	S
62	Y	B	N	N	N	N		H			X	E	S
63	Y	Y	Y	Y	Y	Y		H			X	W	S
64	Y	Y	Y	Y	Y	Y		H		X		W	S
65	Y	Y	Y	Y	Y	Y		H			X	E	S
66	Y	Y	Y	Y	Y	Y		H			X	W	S
67	Y	Y	Y	Y	N	Y		H			X	W	S
68	Y	Y	Y	Y	Y	Y		H			X	S	S
69	Y	Y	Y	Y	Y	Y		H			X	S	B
70	Y	Y	Y	Y	Y	Y		H			X	E	S
71	Y	Y	Y	Y	Y	Y		H		X		E	S
72	Y	Y	Y	Y	Y	Y		H			X	E	S
73	Y	Y	Y	Y	Y	Y		H			X	W	S
74	Y	Y	Y	Y	Y	Y		H			X	E	S
75	Y	Y	Y	Y	Y	Y		Native American			X	S	S
76	Y	Y	Y	Y	Y	Y		H			X	E	B
77	Y	Y	Y	Y	Y	Y		H			X	E	B
78	Y	Y	Y	Y	Y	Y		H			X	W	S
79	Y	Y	Y	Y	Y	Y		H		X		W	S
80	Y	Y	Y	Y	N	Y		H			X	W	S, E
81	Y	Y	Y	Y	Y	Y		H		X		N	S, E
82	Y	Y	Y	Y	Y	Y		H			X	E	S
83	Y	Y	Y	Y	Y	Y		H			X	E	S
84	B	B	B	B	Y	Y		H			X	E	B
85	Y	N	Y	Y	Y	Y		H		X		S	S
86	Y	Y	Y	Y	Y	Y		H		X		S	B
87	Y	Y	Y	Y	Y	Y		H	B	B	B	E	S
88	Y	Y	Y	Y	Y	Y		H		X		E	S

#	Q1	Q2	Q3	Q4	Q5	Q6	Q7 Comments	Ethnicity	Age 18-39	Age 40-59	Age 60 +	Home Area	Language Spoken
89	Y	Y	Y	Y	Y	Y		H			X	W	S
90	N	Y	Y	Y	Y	Y		H			X	E	S
91	Y	Y	Y	Y	Y	Y		H			X	E	S
92	Y	Y	Y	Y	N	Y		H			X	E	S
93	Y	Y	Y	Y	Y	Y		H			X	W	S
94	Y	Y	Y	Y	Y	Y		H, W			X	W	S
95	Y	Y	Y	Y	Y	Y		H			X	E	S
96	Y	Y	Y	Y	Y	Y		H, W		X		W	S
97	Y	Y	Y	Y	Y	Y		H		X		E	S
98	Y	Y	Y	Y	Y	Y		H			X	S	S
99	Y	Y	Y	Y	Y	Y		H			X	S	S
100	Y	Y	Y	Y	Y	Y		H			X	S	S, E
101	Y	Y	Y	Y	Y	Y		H		X		W	S
102	Y	Y	Y	Y	Y	Y		H		X		N	S
103	Y	B	Y	Y	Y	Y		H			X	E	S
104	Y	N	Y	Y	Y	Y		H			X	E	S
105	Y	Y	Y	Y	Y	Y		H			X	E	S
106	Y	Y	Y	Y	Y	Y		H			X	E	S
107	Y	Y	Y	Y	Y	Y		H		X		W	S
108	Y	Y	Y	Y	Y	Y		W			X	W	S
109	Y	Y	N	Y	N	Y		H		X		W	S
110	Y	Y	Y	N	Y	Y		H		X		E, S	B
111	Y	Y	Y	Y	Y	B		H			X	E	S
112	Y	Y	Y	Y	Y	Y		H		X		E	S, E
113	Y	Y	Y	Y	N	Y		H		X		S	E
114	Y	N	N	Y	N	Y		H			X	N	S
115	B	B	Y	B	N	Y		H	X			E	B
116	Y	Y	Y	Y	N	Y		H			X	W	S
117	Y	Y	Y	Y	Y	Y		H			X	W	S
118	Y	Y	Y	Y	Y	Y		H			X	W	S
119	Y	Y	Y	Y	Y	Y		H		X		W	S
120	Y	Y	Y	Y	Y	Y		H		X		E	S
121	Y	B	Y	Y	Y	Y		H			X	E	B
122	Y	Y	Y	Y	Y	Y		H		X		B	S
123	Y	Y	Y	Y	Y	Y		H			X	E	S, E
124	Y	Y	Y	Y	Y	Y		H		X		E	B
125	N	N	N	Y	N	Y		Native American		X		E	S
126	Y	N	Y	Y	Y	Y		H			X	N	S
127	Y	Y	Y	Y	Y	Y		H, W			X	S	S
128	Y	Y	Y	B	B	B		H			X	E	B
129	Y	Y	Y	Y	Y	Y		H		X		N	E
130	Y	Y	N	N	N	Y		H			X	N	E
131	Y	Y	Y	Y	Y	Y		W		X		E	E
132	Y	Y	Y	Y	Y	Y		H		X		N	E

#	Q1	Q2	Q3	Q4	Q5	Q6	Q7 Comments	Ethnicity	Age 18-39	Age 40-59	Age 60 +	Home Area	Language Spoken
133	Y	Y	Y	Y	Y	Y		W			X	S	B
134	Y	Y	Y	Y	Y	Y		A			X	E	E, Urdu, Punjabi
135	Y	Y	Y	Y	Y	Y		H			X	N	E, S
136	Y	Y	Y	Y	Y	Y		H			X	E	B
137	Y	Y	Y	Y	Y	Y		A			X	E	E, Filipino
138	Y	Y	Y	Y	Y	Y		H			X	S	S
139	Y	Y	Y	Y	Y	Y		A		X		W	Tagalog
140	Y	Y	N	Y	Y	Y		Black			X	E	E
141	Y	Y	Y	Y	Y	Y		H			X	S	E
142	Y	Y	Y	Y	N	N		A			X	S	E
143	Y	Y	Y	Y	Y	Y		W			X	S	B
144	Y	Y	Y	Y	N	Y	See comment 1 b	H			X	S	S
145	Y	Y	Y	Y	Y	Y		2 H			X	N	S
146	Y	Y	Y	Y	Y	Y		3 H			X	E	S
147	Y	Y	Y	Y	Y	Y		4 H		X		N	S
148	Y	Y	Y	Y	N	Y		5 H			X	S	S
149	Y	Y	Y	Y	Y	Y		6 H		X		E	S
150	Y	N	N	Y	N	Y		7 H			X	E	S
151	Y	N	Y	Y	Y	Y		8 H			X	E	S, E
152	Y	Y	Y	Y	Y	Y		9 H			X	S	S
153	Y	Y	N	Y	Y	Y		10 H			X	E	S
154	Y	Y	Y	Y	Y	Y		11 H, W		X		S	S
155	Y	Y	B	Y	N	N		12 H			X	E	S
156	Y	N	Y	Y	N	Y		13 H			X	E	S
157	Y	N	Y	Y	B	Y		14 H		X		S	S
158	Y	Y	N	Y	Y	Y		15 H			X	W	S
159	Y	Y	Y	Y	Y	Y		16 H			X	N	S
160	Y	Y	Y	N	N	Y		17 H	B	B	B	E	S
161	Y	Y	Y	Y	N	Y		18 H			X	E	S
162	Y	Y	Y	Y	N	Y		19 H			X	E	S
163	Y	Y	Y	Y	Y	Y		20 H		X		W	S
164	Y	Y	Y	Y	Y	Y		21 Black			X	E	S
165	Y	Y	Y	Y	N	Y		22 H			X	E	S
166	Y	Y	Y	Y	Y	Y		23 H			X	S	S
167	Y	Y	Y	Y	Y	Y		24 H		X		S	S
168	Y	Y	Y	Y	Y	Y		25 H			X	S	B
169	Y	Y	Y	Y	Y	Y		26 H	B	B	B	W	S
170	Y	Y	Y	Y	N	Y		27 H			X	E	S, E
171	B	B	B	B	B	B		28 H			X	E	S, E
172	Y	Y	Y	Y	N	Y		29 H			X	W	S
173	Y	Y	Y	Y	N	Y		30 H			X	S	S
174	Y	Y	Y	Y	Y	Y		31 H			X	W	S
175	Y	Y	Y	Y	Y	Y		32 H			X	W	S
176	Y	N	Y	Y	Y	Y		33 H			X	S, W	S

#	Q1	Q2	Q3	Q4	Q5	Q6	Q7 Comments	Ethnicity	Age 18-39	Age 40-59	Age 60 +	Home Area	Language Spoken
177	Y	Y	Y	Y	Y	Y	34	H			X	W	S
178	Y	Y	N	Y	N	Y	35	H			X	E	S
179	Y	Y	Y	Y	Y	Y	36	H			X	N	S
180	Y	Y	Y	Y	Y	Y	37	H	B	B	B	E	S
181	Y	Y	Y	Y	Y	Y	38	H		X		W	S
182	Y	Y	Y	Y	Y	Y	39	H			X	E	S
183	Y	Y	Y	Y	Y	Y	40	H			X	E	S
184	Y	Y	Y	Y	Y	Y	41	Native American			X	N	S
185	Y	Y	Y	Y	Y	Y	42	H			X	N	S
186	Y	Y	Y	Y	Y	Y	43	H		X		S	S
187	Y	Y	Y	Y	Y	Y	44	H			X	W	S
188	Y	Y	N	Y	Y	Y	45	H		X		W	S
189	Y	Y	Y	Y	Y	Y	46	H			X	W	S
190	Y	Y	Y	Y	Y	Y	47	Native American		X		E	S
191	Y	Y	Y	Y	Y	Y	48	H	B	B	B	S	E
192	N	Y	Y	Y	B	Y	49	A		X		S	Chinese

**TOTALS**

No	5 (3%)	14 (7%)	17 (9%)	6 (3%)	28 (15%)	3 (2%)
Yes	184 (96%)	171 (89%)	170 (88%)	180 (94%)	159 (83%)	186 (97%)
Blank	3 (2%)	7 (4%)	5 (3%)	6 (3%)	5 (3%)	3 (2%)

Hispanic = 175 (91%)  
 Native American = 4 (2%)  
 Asian = 5 (3%)  
 Black = 4 (2%)  
 White = 4 (2%)

North LA/Valley = 24 (13%)  
 South of LA = 42 (22%)  
 East LA/Downtown = 73 (38%)  
 West = 45 (23%)  
 Blank = 4 (3%)

Spanish = 146 (76%)  
 English = 9 (5%)  
 Tagalog = 1 (0.5%)  
 Chinese = 1 (0.5%)  
 Combination or Blank = 34

**COMMENTS:**

- 1 5 No tengo yo que decidir por hotra persona
- 2 Mu interesante lo que nos an dicho
- 3 Devemos copera en las prevas para poidoer tener adulantos en la mediana
- 4 Pienso que se tome radrografia cerebral
- 5 Como familiar defo saber lo que le hacer al paciente
- 6 Yo lo apoyo no solo par mi si no por toda la comunidad y espoer dios los ayude
- 7 Que posibilidad tendrian las personas con alergias a los medicamentos a usar ese tratamiento
- 8 Es beneficios a para nuestra comunidad
- 9 Es muy importante y util lo que estar haciendo. Gracias
- 10 Tenemos se a la ciensia medica hoy dia esta avansada la ciensia medica  
 Agradicinise de todo xonizda(?) toda la explicasion e jm formacion, dios los elumine para poder tener desevas resultadas de todo imbertigacion para el
- 11 uienestor de toda persona dios les elumine ser mente para el bien de nuestra salud. Gracias.
- 12 Muy bien informacion

- 13 Quien responde por una mala practica medica
- 14 Me gustaria una evaluacion
- 15 Todos los estudios que estan haciendo son muy importante para la humanidad
- 16 Comfio en el abancede la ciencia felicitacion a la avence de la medicina
- 17 Mi hija esta en Guatemala y le agarran ataques. 2 beses por se mana despues que fue operada de la cabeza
- 18 Todo me parece bien. Solo por el comentario que el drodio que debe estar de acuerdo
- 19 Todo me parece bien, solo la #5 no por el comentario que el drodio que debe estar la persona de acuerdo.
- 20 Yoga
- 21 Estoy diacuerdo conlodo
- 22 Eso esta bien porque entre mas esprimentos mas se desarrolla el dotorado.
- 23 Creo que este mal tiene que atenderse de inmediato por lo qrabe que es esta enfermel
- 24 Toda la informacion es importante para salvar la vida a una misma y a otras
- 25 5 no tengo familia
- 26 Todo lo que se haga para salvar la vida mervee que su hoga lo mas pronto posible, gracias de ante mano, que dios les berrdiga.
- 27 Todo es correcto lo que ustedes hablan sobre bieno tema gracias
- 28 Para mi todo es correcto. Gracias, por preocuparse. Por nosotros
- 29 Gracias por sus comentarios medicas que son muy importantes por a nosotros.
- 30 Ha sido una informacion explicatise a y necesaria para todos las pacientes
- 31 Gracisas por todo.  
Gracias por benir a este llegar a compartia con nosotros algo tan importante que en verdad emos aprendido algo nuevo en especial para mi pues en mi familia no a susedido a dios gracias.
- 32 familia no a susedido a dios gracias.
- 33 Todo lo que hablo es bueno para nuestro conociemiento para el futuro saber
- 34 Fuera mejor recibir mas explicacion estoy interesada quede en cantada con las classes.
- 35 No porque la decision debe ser personal
- 36 Hoy sido unfrontaicle(?) fura me esta explicacion.
- 37 (Wrote down address)
- 38 Aprova el tratamiento es bueno.
- 39 Me gusto mucho la ensananza, y aprendo lo que no sabia
- 40 Foderma miranda
- 41 De mi porte los felisito por hacer bueno por la umaridad
- 42 Ojala solo lo practiquen a personas que lo necesiteu
- 43 Todo sea para la humanidad y vienestar, de la humanidad
- 44 Que dios los allude y sigun inventanto aparatos para salvar a la gente
- 45 Me parese bien el estuido que estan haciendo
- 46 Stroke Study es good. Estod de acuerdo en este estuido por que es un adilarto de la ciencia
- 47 Me gusto la ensenaza
- 48 Si las venas de hado iszuierdo se inflaman este lo gorgante el pecho es senodeon anbolyo?  
I would like to know if you have procedures to prioritize one treatment from the other, i.e. drain-buster (?) OR cork screw method, before you subject the
- 49 patient to cork screw treatment.