

# Concentric<sup>®</sup> Medical

1380 Shorebird Way  
Mountain View, CA 94043  
phone: 650•938•2100  
toll free: 877•471•0075  
fax: 650•938•2700  
[www.concentric-medical.com](http://www.concentric-medical.com)

December 20, 2002

9 1 3 2 '02 DEC 23 19:37

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 – G020163**

To Whom It May Concern:

In response to a letter dated December 2, 2002, Concentric Medical, Inc., is hereby submitting information in conformance with 21 CFR 50.24(a)(7)(ii). Currently, two (2) sites are enrolling patients using the Waiver of Consent: Columbia University (New York, NY) and University of California, Los Angeles (Los Angeles, CA). Appropriate documentation concerning public disclosure to the communities in which the clinical investigation is being conducted is included with this letter. Should additional sites decide to use the Waiver of Consent, the Agency will be notified as necessary.

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 (650) 938-2100, extension 119.

Sincerely,



Marybeth Gamber  
Senior Regulatory Affairs Specialist  
Concentric Medical, Inc.  
1380 Shorebird Way  
Mountain View, CA 94043  
Phone# (650) 938-2100, ext 119  
Fax# (650) 938-5230  
[Marybeth@Concentric-Medical.com](mailto:Marybeth@Concentric-Medical.com)

95S - DIS8

SUP 24

**New York - Presbyterian Hospital  
The Presbyterian Hospital in the City of New York  
Presbyterian Hospital Community Health Council  
622 West 168th Street  
New York, New York 10032**

March 1<sup>st</sup>, 2002

Paul Papagni, JD  
Executive Director, CPMC, IRB  
Columbia University  
School of Physicians & Surgeons  
620 West 168<sup>th</sup> Street  
New York, NY 10032

Dear Mr. Papagni,

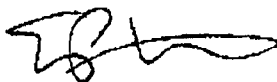
On February 28, 2002, John Pile-Spellman MD, Sundeep Mangia MD and Pierre Cobin MD met with the Community Health Council. They explained their research proposal "A Prospective, Non-Randomized Evaluation of the Concentric Retriever System for the Treatment of Neurovascular Thrombotic Occlusions" (IRB 14138).

They described the CRS and its role in treating acute ischemic strokes particularly, in patients with a contraindication to IV thrombolysis. They explained that in New York State, informed consent differs for treatment and research. And therefore, waiver is needed for patients who, as a result of having suffered acute ischemic strokes, are unable to give consent, are in need of treatment, and who they hypothesize would benefit from CRS.

The Council members expressed their opinion that, as it was explained, CRS is a potentially valuable instrument and this study should proceed. We look forward to hearing about the findings, next year.

The Health Council is comprised of community resident, patients; individuals employed in the community and representatives of the University and hospital.

Sincerely,



Edith M Prentiss  
Chair

212-781-8309  
emprentiss@juno.com

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

