AMERICAN COLLEGE FOR ADVANCEMENT IN MEDICINE INSTITUTIONAL REVIEW BOARD

DATE: November 29, 1995
TO:
FROM: Ralph A. Miranda, MD, FACAM, Chairman - Institutional Review Board
SUBJECT: Monitoring of Protocol Activity
PROTOCOL: Chelation Therapy for Arteriosclerotic Disease
PERIOD MONITORED: November 5, 1994 through November 5, 1995
The ACAM Institutional Review Board (IRB) is responsible for the ongoing monitoring of your use of protocols which have been approved by this IRB. Please answer the questions below and return this form and any attachments along with your annual \$100 update fee within 10 days to Dr. Ralph Miranda, IRB Chairman, c/o IRB Secretary, 23121 Verdugo Drive, Suite 204, Laguna Hills, CA 92653.
NOTE: If this study has been terminated, please attach a written statement with the date and reason for termination/suspension of the study. Include copies of any relevant correspondence substantiating closure.
1. Please attach a copy of the consent form currently in use for this protocol.
2. If there have been any changes in the consent form from the previously filed version, please attach a written description of those changes. If there have been no changes, write "no change" here:
3. If there have been any changes in the protocol from the previously filed version, please attach a written description of those changes. If there have been no changes, write "no change" here:
Please answer the following questions regarding your protocol during the monitoring period:
A. Number of male subjects enrolled in study
B. Number of female subjects enrolled in study
C. Number of subjects in study who are: Minors Prisoners
Pregnant Women Mentally Retarded Mentally Disabled
D. Any adverse reactions noted? YES NO (circle one)
Note: If yes, you must attach a written description of those adverse reactions. Adverse reactions must be reported to this IRB Chairman immediately!

AMERICAN COLLEGE FOR ADVANCEMENT IN MEDICINE INSTITUTIONAL REVIEW BOARD PROTOCOL MONITORING Page 2

- E. Please attach a written description of the benefits obtained to date from this study.
- F. Please attach a written description of problems associated with obtaining subjects for the project/protocol and/or informed consent.

5.	If there has been any additional new description. If none, write "none" he	information obtained in the monitorere:	red period, please attach a writter
6.	If there are any anticipated modificat If none, write "none" here:	tions to the project/protocol, please	attach a written description.
Th	ank you.		

•	via 1 AAC (hard copy in man - 5 pages)			
Ľ	DATE:	July 3, 1998		
T	o:			
F	ROM:	Ralph A. Miranda, MD, FACAM, Chairman - Institutional Review Board		
S	UBJECT:	Monitoring of Protocol Activity		
	ROTOCOL: ERIOD:	Chelation Therapy for Arteriosclerotic Disease		
	ONITORED:	November, 1996 through November, 1997		
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3.	. If there have been any <u>changes</u> in the <u>protocol</u> from the previously filed version, please attach a written description of those changes. If there have been no changes, write "no change" here:			
4. Please answer the following questions regarding your protocol during the monitoring period:		r the following questions regarding your protocol during the monitoring period:		
	A. 1	Number of male subjects enrolled in study		
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	C. 1	Number of subjects in study who are: Minors Prisoners		
	F	regnant Women Mentally Retarded Mentally Disabled		
	D. A	any adverse reactions noted? YES NO (circle one)		
		lote: If yes, you must attach a written description of those adverse reactions. Adverse reactions must be reported to this IRB Chairman immediately!		

Via FAX (hard o	copy in mail - 3 pages)		
DATE:	ATE: October 1, 1998		
TO:			
FROM:	Ralph A. Miranda, MD, FACAM, Chairman - Institutional Review Board		
SUBJECT:	Monitoring of Protocol Activity		
PROTOCOL:	Chelation Therapy for Arteriosclerotic Disease		
PERIOD: MONITORED:	November, 1997 through November, 1998		
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I	Pregnant Women Mentally Retarded Mentally Disabled		
D. 1	Any adverse reactions noted? YES NO (circle one)		
<u>]</u>	Note: If yes, you must attach a written description of those adverse reactions. Adverse reactions must be reported to this IRB Chairman immediately!		

Via FAX (har	d copy in mail - 3 pages)	
DATE:	February 14, 2000	
TO:		
FROM:	Ralph A. Miranda, MD, FACAM, Chairman - Institutional Review Board	
SUBJECT:	Monitoring of Protocol Activity	
PROTOCOL:	Chelation Therapy for Arteriosclerotic Disease	
PERIOD: MONITORED	November, 1998 through May, 2000	
which have be	stitutional Review Board (IRB) is responsible for the ongoing monitoring of your use of protocols on approved by this IRB. Please answer the questions below and return this form and any long with your annual \$100 update fee within 10 days to Dr. Ralph Miranda, IRB Chairman, ary, ACAM, 23121 Verdugo Drive, Suite 204, Laguna Hills, CA 92653.	
NOTE: If this termination/sus	study has been terminated, please attach a written statement with the date and reason for spension of the study. Include copies of any relevant correspondence substantiating closure.	
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26. If there have description	re been any <u>changes</u> in the <u>consent form</u> from the previously filed version, please attach a written of those changes. If there have been no changes, write "no change" here:	
27. If there hav description	e been any <u>changes</u> in the <u>protocol</u> from the previously filed version, please attach a written of those changes. If there have been no changes, write "no change" here:	
28. Please ansv	ver the following questions regarding your protocol during the monitoring period:	
A.	Number of male subjects enrolled in study	
B.	Number of female subjects enrolled in study	
C.	Number of subjects in study who are: Minors Prisoners	
y.	Pregnant Women Mentally Retarded Mentally Disabled	
D.	Any adverse reactions noted? YES NO (circle one)	
	Note: If yes, you must attach a written description of those adverse reactions. Adverse reactions must be reported to this IRB Chairman immediately!	

Via FAX (hard	copy in mail - 3 pages)	
DATE:	February 21, 2001	
TO:		
FROM:	Ralph A. Miranda, MD, FACAM, Chairman - Institutional Review Board	
SUBJECT:	Monitoring of Protocol Activity	
PROTOCOL:	Chelation Therapy for Arteriosclerotic Disease	
PERIOD: MONITORED:	May, 2000 through May, 2001	
which have been attachments ale	itutional Review Board (IRB) is responsible for the ongoing monitoring of your use of protocols approved by this IRB. Please answer the questions below and return this form and any ong with your annual \$100 update fee within 10 days to Dr. Ralph Miranda, IRB Chairman, y, ACAM, 23121 Verdugo Drive, Suite 204, Laguna Hills, CA 92653.	
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C. 1	Number of subjects in study who are: Minors Prisoners	
I	Pregnant Women Mentally Retarded Mentally Disabled	
D. <i>A</i>	Any adverse reactions noted? YES NO (circle one)	
. 1	Note: If yes, you must attach a written description of those adverse reactions. Adverse reactions must be reported to this IRB Chairman immediately!	