

GREAT LAKES COLLEGE OF CLINICAL MEDICINE
Institutional Review Board
L. Terry Chappell, M.D. - Secretary
122 Thurman Street - Bluffton, Ohio 45817
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Letter of Termination

Project M021 L. Terry Chappell, M.D. EDTA Chelation and
Coronary Artery Disease Patient Registry

January 15, 2001

L. Terry Chappell, M.D.
122 Thurman St Box 248
Bluffton, OH 45817

Dear Doctor Chappell:

This letter is to inform you that the IRB must *terminate* your above project *effective immediately* as requested by the FDA due to the reason that "*the IRB could not determine whether an Investigational New Drug (IND) is required*" (partial copy of letter is enclosed.)

As investigator, you are required to continue monitoring study subjects for adverse events, but must immediately cease administrations of investigational medical devices by human subjects pending review and approval by another IRB.

Please return written acknowledgement that the study was terminated STAT, and that all co-investigators have been notified.

Sincerely,

James Carter
James Carter, M.D.
Chairman

Feel Better!
**CELEBRATION
OF
HEALTH
C E N T E R**

L. Terry Chappell, M.D.* • Richard Radnovich, D.O.



January 16, 2001

Jack Young, MD
13450 Hibiscus Ave
Winter Park, FL 32789

Dear Doctor

The GLCCM IRB has been informed by the FDA to terminate the EDTA Chelation & Coronary Artery Disease Patient Registry for the reason the IRB could not determine whether and IND was required.

As investigators you are required to continue monitoring study subjects for adverse events, but must immediately cease administrations of investigational drugs and use of investigational medical devices by human subjects pending review and approval by another IRB.

Please return written acknowledgement that you as a co-investigator have been notified immediately. Fax copies are excepted.

Sincerely,

L. Terry Chappell, M.D.

LTC/bta

Registry/letter to terminate

Feel Better!

**CELEBRATION
OF
HEALTH
C E N T E R**

L. Terry Chappell, M.D.* • Richard Radnovich, D.O.



January 16, 2001

James Carter, MD
3501 Severn
#19
Metairie, LA 70002

Dear Doctor

The GLCCM IRB has been informed by the FDA to terminate the EDTA Chelation & Coronary Artery Disease Patient Registry for the reason the IRB could not determine whether and IND was required.

As investigators you are required to continue monitoring study subjects for adverse events, but must immediately cease administrations of investigational drugs and use of investigational medical devices by human subjects pending review and approval by another IRB.

Please return written acknowledgement that you as a co-investigator have been notified immediately. Fax copies are accepted.

Sincerely,

A handwritten signature in cursive script that reads "L. Terry Chappell, M.D." The signature is written in dark ink and is positioned above the printed name.

L. Terry Chappell, M.D.

LTC/bta

Registry/letter to terminate

122 Thurman Street • Box 248 • Bluffton, Ohio 45817-0248
Phone: 419-358-4627 • Fax: 419-358-1855 • Toll Free: 800-788-4627

Feel Better!
**CELEBRATION
OF
HEALTH
C E N T E R**

L. Terry Chappell, M.D.* • Richard Radnovich, D.O.



January 16, 2001

Tammy Born, DO
3700 52nd St
Grand Rapids, MI 49512

Dear Doctor

The GLCCM IRB has been informed by the FDA to terminate the EDTA Chelation & Coronary Artery Disease Patient Registry for the reason the IRB could not determine whether and IND was required.

As investigators you are required to continue monitoring study subjects for adverse events, but must immediately cease administrations of investigational drugs and use of investigational medical devices by human subjects pending review and approval by another IRB.

Please return written acknowledgement that you as a co-investigator have been notified immediately. Fax copies are ~~not~~ accepted.

Sincerely,

L. Terry Chappell, M.D

LTC/bta

Registry/letter to terminate

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