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 243
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, M.D.
Chairman
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 an 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
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 an 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,

L. Terry Chappell, M.D.

LTC/bta

Registry letter to terminate
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 accepted.

Sincerely,

[Signature]

L. Terry Chappell, M.D

LTC/bta

Registry/letter to terminate