# CHAPTER 6

# ORGANIZATIONAL STRUCTURE AND POLICY MATTERS

## 6.1 INTRODUCTION

The participating investigators and centers in the Thrombolysis in Myocardial Ischemia Trial (T3) collaborate through a study organization which is designed to maintain continuity of operations in the study and to facilitate effective communication and cooperation among the various functional units. Exhibits 6-1 and 6-2 summarize the study organization and the relationships among the participating units.

## 6.2 PARTICIPATING UNITS

### 6.2.1 NHLBI, Division of Heart and Vascular Diseases

The NHLBI oversees the conduct and provides routine grants management activities, as it does for all investigator-initiated grants. NHLBI staff named the members of the Data and Safety Monitoring Board and also serve on this Committee. Members of NHLBI Program Office are represented on the Steering, Executive, and Operations Committees of T3.

### 6.2.2 Study Chairman's Office (SCO)

Dr. Eugene Braunwald is the Study Chairman of T3 and has major responsibility for and is accountable for the scientific direction and administration of the trial.

The Study Chairman's duties are:

1. To develop and maintain, with advice from other study participants, an internal organizational structure that meets the needs of the study;
2. To be informed about all aspects of the study operations and, using the study organization developed, formulate study policy and take action as necessary to ensure the smooth operation of the study;
3. To appoint study participants to appropriate positions and committees as needed;
4. To serve as Chairman of the T3 Executive Committee, Steering Committee, and Operations Committee; and

5. To serve as an ex-officio member of the Data and Safety Monitoring Board.

The Study Chairman will serve for the duration of the study. In the event that the Study Chairman is unable to serve because of resignation, death, or serious illness, the NHLBI Director will appoint a new Chairman. Prior to appointment of a new Chairman, the Data and Safety Monitoring Board will appoint an Interim Chairman.

Staff in the Study Chairman's Office have primary responsibility for the day-to-day managerial activities of the office. They refer all incoming queries or problems from the Clinical Centers and Core Laboratories to the appropriate person(s) and provides timely resolutions, assist the Study Chairman in the design and development of issues that arise, assist in patient recruitment techniques, alterations of study forms and Manual of Operations, organize and schedule with the Data Coordinating Center (DCC) all committee meetings and participate in site visits to the Clinical Centers and Core Laboratories with members from the DCC for quality control activities during the course of the study. They will also participate in the preparation of end point and data bank studies under the direction of the Study Chairman.

### 6.2.3 Data Coordinating Center (DCC)

The Maryland Medical Research Institute (MMRI) located in Baltimore, Maryland is the Data Coordinating Center (DCC) for T3.

Staff at the DCC have primary responsibility for the statistical design, data entry, data management, statistical analyses, and for implementing quality control measures to ensure the quality and accuracy of data collected. The DCC staff developed the Manual of Operations, designed the study forms, prepared study size calculations, and prepared the appropriate randomization sequencing and treatment assignments. The DCC staff are also responsible for distributing to all Investigators and Research Coordinators regular progress reports and Steering Committee minutes, for preparing necessary reports for the Data and Safety Monitoring Board including the monitoring of study end points and adverse drug reactions, and for collaborating with Study Investiga-

tors in the performance of end point and data bank studies. The DCC staff will collaborate with other study Investigators in the writing and review of study manuscripts. The DCC staff also assist with training of Clinical Center staff.

6.2.4 Operations Committee

The Operations Committee oversees the operational aspects of the study and is comprised of the Study Chairman, the Director of the Data Coordinating Center and representatives of the Study Chairman's Office, the Data Coordinating Center and NHLBI. This committee has regular conference calls to review patient recruitment, protocol violations, and study issues. This committee reports to the Executive Committee and to the Steering Committee on all matters of significance regarding conduct of the study.

6.2.5 Executive Committee of the Steering Committee

The Executive Committee addresses scientific and policy issues of the trial. It is comprised of the members of the Operations Committee, the directors of the Core Laboratories, a representative of the Canadian Centers participating in the study, a representative of the Research Coordinators, and three elected representatives from the Clinical Centers. The Executive Committee discusses scientific considerations related to the conduct of the study and makes recommendations to the Steering Committee.

6.2.6 Steering Committee

The Steering Committee is comprised of the members of the Executive Committee, the Investigators of each T3 Clinical Center, the Core Laboratories, and the Data Coordinating Center and representatives of the NHLBI. This committee is responsible for the overall scientific direction of the study and convenes twice each year to assess the trial's progress. The Steering Committee holds responsibility for modifying and appropriately executing the Protocol. The committee has developed performance standards for evaluation of Clinical Centers.

### 6.2.7 Clinical Centers and Satellites

Forty Clinical Centers with one or more participating hospitals participate in T3. The majority of the Clinical Centers are affiliated with major university hospitals in the United States and six are located in Canada. Clinical Center Investigators and staff are responsible for the screening and the recruitment of eligible patients; randomization and administration of study medications; daily monitoring of Protocol end points; cardiac catheterization and, if appropriate, performance of percutaneous transluminal coronary angioplasty (PTCA) and coronary artery bypass graft surgery (CABG); standard medical care; follow-up contact to ascertain health status; and for the collection of all data required by the T3 Protocol. A Clinical Center Principal Investigator who has recruited other hospitals to collaborate as "Satellites" assumes responsibility for the conduct of the Protocol with Co-Investigators from the affiliated hospital. Investigators and Research Coordinators from affiliated hospitals will screen and recruit patients for T3 in a manner identical to that employed in the hospital of the Clinical Center. Investigators at affiliated hospitals may perform PTCA and/or CABG, provided they are certified for these procedures by the Qualitative Angiography Core Laboratory. Co-equal hospitals are those capable of providing the full range of data collection and therapeutic maneuvers of T3.

### 6.2.8 Core Laboratories

A total of six Core Laboratories are participating in the T3 studies. These are described below.

#### 6.2.8.1 Quantitative Angiographic Core Laboratory

The Quantitative Angiographic Core Laboratory is located at the University of Washington in Seattle, Washington. This Core Laboratory is responsible for the quantitative measurements of the cineangiograms performed in the T3A Clinical Centers. It is also responsible for ensuring that each Clinical Center is able to obtain reproducible and high-quality radiographic data.

This laboratory receives, reviews, and analyzes all radiographic data on all enrolled patients from each of the T3A Clinical Centers and transmits resultant data to the DCC. In addition, it monitors the quality, completeness, and timeliness of the T3 radiographic procedures conducted at the Clinical Centers.

6.2.8.2 Electrocardiographic Core Laboratory

The ECG Core Laboratory is located at the St. Louis University School of Medicine in St. Louis, Missouri. The primary goals of this core facility are to ensure quality performance of ECG's at the Clinical Centers and for providing central, computerized, interpretation of all protocol-required ECG's as well as for interpreting exercise treadmill test results. Timely submission of these data to the DCC is also provided.

6.2.8.3 Holter Monitoring Core Laboratory

The Holter Monitoring Core Laboratory is located at the Brigham and Women's Hospital in Boston, Massachusetts. The primary responsibilities are to interpret Holter recordings from all enrolled patients at each participating hospital and to provide timely interpretation of ST-segment evidence of myocardial ischemia to physicians caring for the patient and to the DCC.

6.2.8.4 Qualitative Angiography Core Laboratory

The Qualitative Angiography Core Laboratory is located at Brown University in Providence, Rhode Island. It provides independent qualitative interpretation of cineangiograms and results of PTCA. All angioplasty operators must be certified by this Core Laboratory to perform angioplasty on T3 patients.

6.2.8.5 Thallium Core Laboratory

The Thallium Core Laboratory is located at Yale University School of Medicine in New Haven, Connecticut. Responsibilities include ensuring that each Clinical Center (and affiliated hospitals) are able to obtain reproducible high-quality thallium images. This laboratory receives, interprets, and analyzes thallium data from patients enrolled and sends to the DCC composite results on a timely basis. Monitoring of the Clinical Centers for quality,

completeness, and timeliness of T3 thallium imaging tests is also performed by this laboratory.

6.2.8.6 Coagulation Core Laboratory

The Coagulation Core Laboratory is located at the University of Vermont, Burlington, Vermont. It has responsibility for analysis of blood specimens shipped from the Clinical Centers.

6.2.9 Drug Distribution Center

The Drug Distribution Center is located at the Veterans Administration Hospital in Albuquerque, New Mexico. The Center has responsibility for distribution of study drug kits to the Clinical Centers.

6.2.10 Subcommittees of the Steering Committee

6.2.10.1 Data Bank and Ancillary Studies Subcommittee

This Subcommittee reviews and approves all proposals submitted for data bank and ancillary studies (see Section 6.3). It is comprised of members of the Steering Committee and its functions are described below under "Guidelines for Publications and Presentations." The members of the Subcommittee were appointed by the Operations Committee.

6.2.10.2 Mortality and Morbidity Classification Committee (MMCC)

This committee is responsible for developing standardized procedures to classify cause of death and evidence for nonfatal myocardial infarction. This committee is comprised of individuals who are not participating in the care of patients at T3 Clinical Centers. Members are blinded with regard to experimental treatment received by each of the study patients.

6.2.10.3 Hemorrhagic Event Review Committee

This committee is responsible for classification of each hemorrhagic event occurring during the initial T3 hospitalization. Members of this committee were recruited from T3 Clinical Centers.

6.2.10.4 Writing Subcommittees

As end point data become available for presentation and publication, writing committees comprised of members of the Steering Committee will be formed. The Executive Committee will appoint these Writing Subcommittees with the approval of the Study Chairman.

6.2.11 Data and Safety Monitoring Board

The Data and Safety Monitoring Board is comprised of an independent group of experts, including senior scientists, cardiologists, a biostatistician, a hematologist, and an ethicist. The Study Chairman and the Director of the Data Coordinating Center participate as ex-officio members. The Director of the Division of Heart and Vascular Diseases of the NHLBI named the members of this committee and serves as an ex-officio member. The Data and Safety Monitoring Board meets at least twice a year. Its primary role is to review the trial goals and protect the scientific integrity of the trial as described below:

1. Review of any significant changes in the design or operation of the study recommended by the Steering Committee;
2. Review of the overall performance, progress, and findings at regular specified intervals; and
3. Formulation of recommendations to the NHLBI for continuation or termination of the study based on evidence of beneficial or adverse effects of therapy or on the enrollment of sufficient number of patients.

6.3 END POINT, DATA BANK, AND ANCILLARY STUDIES

6.3.1 Introduction

The Steering Committee has primary responsibility for all end point, data bank, and ancillary studies (defined below) as well as for all publications and presentations evolving from T3.

Investigators at all T3 sites, including the Core Laboratories and the DCC, have equal status with regard to developing protocols, participating in such studies as approved by the Steering Committee, and collaborating in the

development and publication of research papers based on T3 material. With the approval of the Study Chairman, associate investigators at the various sites are encouraged to participate in this process. The Steering Committee will develop standards for regular evaluation of the performance of the Clinical Centers in this area.

T3 Investigators proposing studies that require the collaboration of one or more of the T3 Central Units (e.g., Core Laboratories or the DCC) should contact the appropriate individuals prior to submission of a given proposal. The appropriate staff in the Central Units will participate in drafting the proposal, indicate willingness to participate, and identify sources of funding to support the level of effort required for the project.

The DCC should be consulted in the development and analysis of protocols that require review of accumulated data from the Clinical Centers or data on file at the DCC. The biostatistical services of the members of the DCC are available in designing and carrying out all T3 research.

### 6.3.2 Purpose of Procedural Guidelines

The procedures for end point, data bank, and ancillary studies and for publication of T3 research results are given in detail in Section 6.3.4. These procedures are intended to protect the interests of all participants in the trial, to assure that study data conform to the requirements of study design and are accurately presented, that authorship is appropriately acknowledged, and that the text of each publications is well-written.

### 6.3.3 Types of T3 Research

T3 research and the resulting presentations and publications may be grouped into the following categories:

1. End point studies,
2. Data bank studies,
3. Ancillary studies, and
4. Independent studies.

Distinctions among these types of studies as well as among independent studies are given below. Research other than end point studies may be

conducted prior to the end of the T3 investigation and is strongly encouraged, so that the maximum information can be obtained from this trial.

6.3.3.1 End Point Studies

An end point study is a study that pertains to the fundamental goals of T3 or that involves data (such as treatment assignment, success rates of thrombolysis and revascularization, differences in failure of therapy by treatment assignment, or mortality rates) which cannot be released prior to the end of the study. These studies will summarize the findings based on the entire study population and will be written at the conclusion of the project.

6.3.3.2 Data Bank Studies

A data bank study uses data, specimens, or recordings, which are routinely collected on patients who are logged, screened, or randomized into T3. Analysis of these data are used to answer a specific scientific question. Data used in this research are not directly related to the fundamental goals of the study (e.g., the efficacy of T3 experimental strategies). Data bank studies must be approved by the Data Bank and Ancillary Studies Subcommittee and reports from these studies should be reviewed prior to presentation or publication following the procedure outlined below.

6.3.3.3 Ancillary Studies

An ancillary study uses supplementary data that are collected on patients who are logged, screened, or randomized into T3, over and above the data collection required by the T3 protocol. Such studies are restricted to consideration of a specific test technique or involve only supplemental data collected on T3 patients. Ancillary studies must be reviewed and approved by the Executive Committee and ratified by the Steering Committee prior to initiation to ensure that they do not conflict with the main protocol. Review by the T3 Data Bank and Ancillary Study Subcommittee of the T3 Steering Committee is required for presentation or publication of an ancillary study.

6.3.3.4 Independent Studies

It is understood that each Clinical Center has the right to conduct studies that are independent of the T3 study in patients who do not meet the criteria for randomization into T3. However, T3 participants agree not to conduct an independent study of the efficacy of a thrombolytic agent or the strategy under investigation by T3 in eligible patients during the period of active recruitment for T3.

6.3.4 Guidelines for Publications and Presentations

The Steering Committee has primary responsibility for all publications and presentations resulting from T3.

No abstract or paper resulting from T3 research shall be presented or submitted for publication without having progressed through this review process, as approved by the T3 Steering Committee.

As noted above, T3 research and the resulting presentations and publications will be grouped into the following categories:

1. End point studies,
2. Ancillary studies, and
3. Data bank studies.

The procedures for each type of study are given below.

6.3.4.1 End Point Studies

6.3.4.1.1 Procedures for Initiation and Approval of these Studies

End point studies will generally involve the collaboration of many investigators and review of the manuscript by experts in several scientific specialties. Consequently, in most cases, Writing Subcommittees will be designated by the Executive Committee of the Steering Committee on an ad hoc basis for preparation of these abstracts and manuscripts on behalf of the T3 Study Group.

Proposals for end point studies may be introduced and developed by any member of the Steering Committee. Such proposals will be considered by the Executive Committee of the Steering Committee.

6.3.4.1.2 Conduct of this Research

After approval of a proposed end point study, members will be elected or invited to serve on an ad hoc Writing Subcommittee and a Chairperson chosen. These investigators will work with the DCC staff to conduct the interactive data analysis needed to investigate the question at hand and prepare a manuscript based on these findings. Every effort will be made by the Subcommittee to consider and incorporate comments and suggestions from the larger Steering Committee in this manuscript. Often the Subcommittee members may meet with members of the Data Coordinating Center or other T3 Clinical Centers for development of these papers.

6.3.4.1.3 Restrictions on which Data may be Released

T3 end point data or data which might jeopardize the blinding of therapy or continuation of the project will not be released to T3 Investigators or the public until the end of the study, at a time deemed appropriate by the T3 Data and Safety Monitoring Board, the National Heart, Lung, and Blood Institute and the Study Chairman.

6.3.4.1.4 Authorship

Publications pertaining to the fundamental goals (end points) of the study, involving randomized patients, will have authorship identified on the byline as "the T3 Investigators." Individuals who contributed specific sections of the publication and members of the ad hoc Writing Subcommittee which prepared the manuscript will be identified in appropriate footnotes. An appendix listing all Principal and Co-Investigators will be included at the end of the manuscript's text.

6.3.4.1.5 Review and Approval of Manuscripts and Abstracts Prior to Presentation and Publication

Every end point study manuscript considered suitable for publication will be submitted by the Chairperson of the Writing Subcommittee to the T3 Study Chairman, who will be responsible for arranging and implementing review according to the following procedures.

1. The manuscript will be forwarded promptly to at least two reviewers selected from the members of the Steering Committee or their associates, with the request to respond within two weeks with a detailed critical review of the manuscript. Outside reviewers may be selected when appropriate.
2. Reviews will be forwarded to all members of the ad hoc Writing Subcommittee without the reviewers being identified, with a request for appropriate revision and response.
3. The Writing Subcommittee will be expected to respond to the review in a reasonable period of time, forwarding to the Study Chairman the revised manuscript with a letter commenting in detail on the points raised by the reviewers.
4. After review, the Study Chairman will return the manuscript to the Writing Subcommittee for final comments or changes.
5. If acceptable, the completed manuscript will then be submitted for publication.

6.3.4.2 Ancillary Studies

6.3.4.2.1 Approval

Ancillary study proposals will be reviewed by the Data Bank and Ancillary Studies Subcommittee to ensure that the proposed study does not conflict with the primary goals of the study. Ancillary studies must also be approved by the Executive Committee before the investigators begin work on such studies.

6.3.4.3 Data Bank Studies

6.3.4.3.1 Procedure for Initiation and Approval

Data bank studies must be approved by the Data Bank and Ancillary Study Subcommittee of the T3 Steering Committee. Before beginning a data bank project, a protocol initiated by one or more of the T3 Investigators and/or their associates should be submitted to this Subcommittee for consideration. The Chairperson of the Subcommittee will notify the Investigator and the Study Chairman when the project is approved.

6.3.4.3.2 Conduct of this Research

After approval is given by the Data Bank and Ancillary Study Subcommittee, the Principal Investigators (on the data bank project) will work with the Data Coordinating Center staff to conduct the data analysis.

6.3.4.3.3 Restrictions on Which Data May be Released

Prior to the end of the study, data directly related to the key study end points (namely, evaluation of the efficacy of t-PA and treatment strategies) or data which might jeopardize the blinding or continued conduct of the trial will not be released to investigators for data bank research.

6.3.4.3.4 Priorities for Work

Because of the routine work load at the DCC, it will be necessary to establish priorities for data processing. Therefore, the DCC will, as necessary, conduct analyses on data bank studies in the order in which they have been approved or seek guidance from the Executive Committee for determining priorities for analysis.

6.3.4.3.5 Authorship

After a data bank study proposal is approved by the Data Bank and Ancillary Study Subcommittee, its research and development are the responsibility of the identified investigators on the project. Authorship decisions on T3 data bank studies should take into account the unique cooperative effort that has produced the results. For clinical papers in particular, authorship should be offered to individuals from Clinical Centers, Core Laboratories, and Data Coordinating Center when their contributions are appropriate. On the other hand, there will be papers of more limited scope which probably do not warrant a large number of authors. The following mechanism will be utilized to determine authorship:

a. The lead author will propose a list of co-authors, based on the above guidelines.

b. The Chairman of the Data Bank and Ancillary Study Subcommittee, and the T3 Study Chairman, will review and approve, or make recommendations regarding alterations in the proposed list of authors.

The names of these investigators will be followed by the designation "and the T3 Study Group" on the byline.

6.3.4.3.6 Review and Approval of Manuscripts and Abstracts Prior to Publication or Presentation

The Data Bank and Ancillary Study Subcommittee and the Study Chairman's Office, on behalf of the Steering Committee, will review all data bank study abstracts and manuscripts prior to submission for publication or presentation. All abstracts must be received by the Subcommittee members, Operations Committee, all co-authors, the T3 Study Chairman, and Data Coordinating Center at least three weeks prior to the submission deadline. Manuscripts produced by data bank studies must be received by these reviewers at least one month (30 days) before the scheduled submission date. After review, the Subcommittee will decide, in consultation with the DCC, if release for publication is appropriate. The Chairperson of the Subcommittee will then notify the authors and the T3 Study Chairman's Office of its decision within one month of the receipt of a manuscript, and within one week for abstracts. The paper may then be sent immediately to the publisher.

6.3.4.4 Other Research

6.3.4.4.1 Major Monographs on T3 Study Design

Manuscripts concerning the T3 study's overall design, protocol, procedures, or organizational structure which do not involve end point data or data collected on T3 patients may be published prior to the end of the study. Such major publications will be developed and reviewed according to the same guidelines used for end point studies.

6.3.4.4.2 Presentations on T3 Study Design Features

Many public presentations or publications about T3 which involve no end point, ancillary, or data bank study data (e.g., grand rounds talks concerning the study's general design and objectives) will not require formal preliminary

review and approval by the Data Bank and Ancillary Study Subcommittee. However, if there is any doubt, investigators are asked to consult with the Study Chairman's Office indicating their intention to publish or present the material, in order to avoid the premature release of T3 data or the inappropriate publication of confidential information.

## 6.4 CONFLICT OF INTEREST

### 6.4.1 Policy for Prevention of Real or Apparent Conflict of Interest in the Thrombolysis in Myocardial Ischemia Trial

In response to the request of the NHLBI, the T3 Investigators developed and agreed to the following statement:

> To insure that the Thrombolysis in Myocardial Ischemia Trial is not called into question due to actual or perceived conflict of interest, the participating investigators voluntarily agree to abide by each of the guidelines described in this policy statement. The statement for the Thrombolysis in Myocardial Ischemia Trial is an adaptation of the Conflict of Interest Guidelines for the Post Coronary Artery Bypass Graft Surgery Multicenter Clinical Trial, an NHLBI trial; the latter guidelines were published in the New England Journal of Medicine 320:949-951 (April 6) 1989. The T3 Investigators are in agreement with the view of the Post Coronary Artery Bypass Surgery Study Investigators that since "investigators are responsible for the final analysis and interpretation of the data, the absence of financial interest in the drugs they are testing or the companies that manufacture those drugs is both prudent and appropriate."

### 6.4.2 Individuals to be Governed by Conflict of Interest Guidelines

Members of the investigative group who are governed by these guidelines include the Study Chairman, Principal Investigator of the Data Coordinating Center, Principal Investigators of the Core Laboratories, and the Principal Investigator at each Clinical Center and its affiliated hospital(s). Co-investigators at a Clinical Center or affiliated hospital playing a major role in the conduct of the study will also be governed by these guidelines if deemed appropriate by the Clinical Center's Principal Investigator. In

addition, all professional personnel receiving financial support from the NIH for activities pertinent to the trial will also be governed by these guidelines. The spouse and dependents of each of the aforementioned persons will also be subject to these guidelines.

6.4.3 Time Period for Maintenance of the Conflict of Interest Policy

The guidelines set forth in this policy will commence at the start of patient recruitment and will terminate one year following the public presentation of the principal results.

Investigators not privy to end point data and discontinuing participation in the trial during recruitment will be subject to these guidelines until one year following their departure from the study.

6.4.4 Financial Guidelines

1. The T3 Investigators agree not to own, buy, or sell stock or stock options during the aforementioned time period in any of the pharmaceutical companies* with products being tested in this trial, or who have provided financial support for the study.
2. The investigators agree not to serve as paid consultants to any of these companies during the aforementioned time period.
3. The Data Coordinating Center will maintain conflict of interest statements updated annually from each investigator.

Activities not viewed as conflict of interest, but to be reported annually to the Data Coordinating Center include:

1. Participation of investigators in educational activities that are supported by the companies.
2. Participation of investigators in other research projects supported by these companies.
3. Occasional scientific counsel to the companies on issues not related to the products in the trial and for which there is no financial payment or other compensation.

*Companies include: Genentech, Inc., CIBA-GEIGY Corporation, Marion Laboratories, Inc., SmithKline Pharmaceuticals, and Mallinkrodt, Inc.

4. Financial interests in these companies, over which the investigator has no control, such as mutual funds or blind trusts.

6.4.5 Reporting of Financial Disclosures and Other Activities

The investigators agree to update their financial disclosures (Exhibit 6-3) and related activities as described above on an annual basis and submit these data to the Data Coordinating Center. The Data Coordinating Center will maintain the confidentiality of these records and present them to a review committee on a regular basis. In the case of actual or perceived conflict of interest, the Study Chairman will bring it to the attention of the NHLBI and the Data and Safety Monitoring Board.

6.4.6 Review of Policy Statement

The investigators agree to review on a regular basis these guidelines and take any additional steps to insure that the scientific integrity of the trial remains intact.

EXHIBIT 6-1

LINES OF RESPONSIBILITY

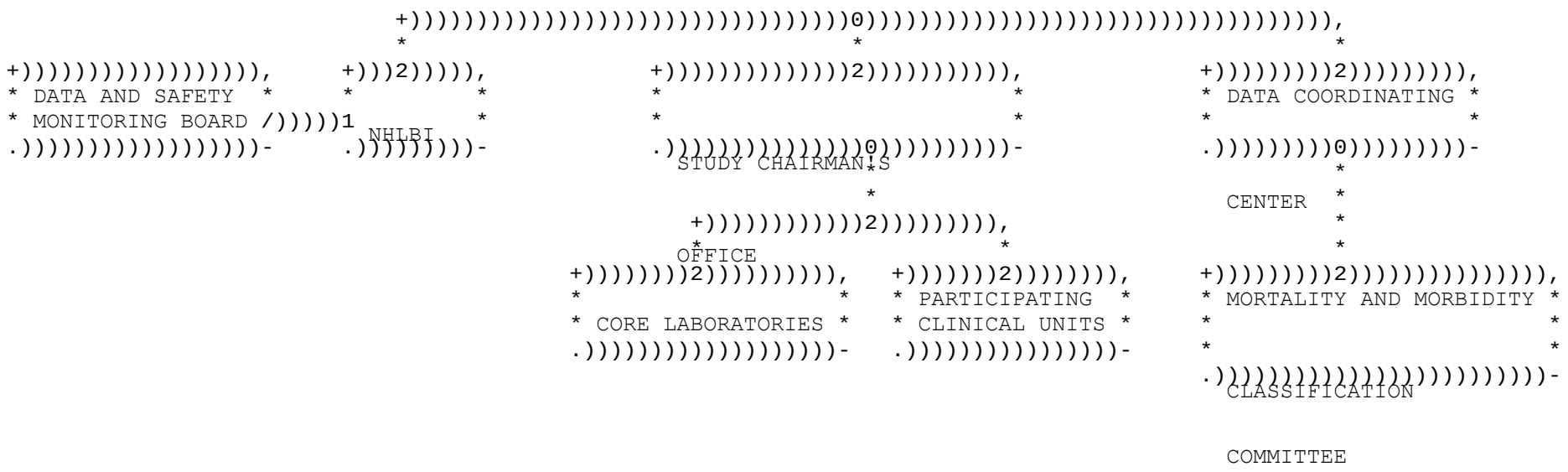

EXHIBIT 6-2

ADMINISTRATIVE STRUCTURE

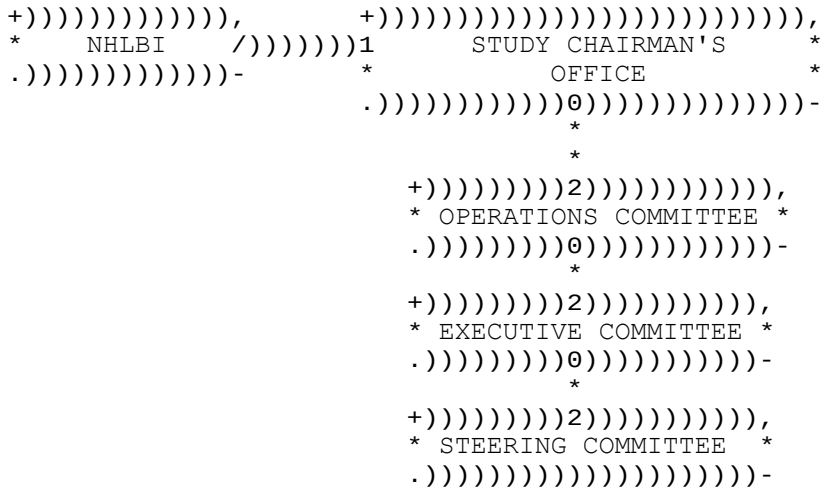

EXHIBIT 6-3

INITIAL FINANCIAL DISCLOSURE STATEMENT

The undersigned certifies that:

1. Neither I, nor my spouse, nor my dependents currently hold stock or stock options in any of the companies* providing medication or financial support in the trial as of _____ _____.

2. Neither I, nor my spouse, nor my dependents are currently paid consultants from any of the companies* providing medication or financial support in the trial as of _____ _____.

If response(s) is no to questions 1 and 2, an explanation is required.

_____ _____

Investigator (typed name)

Investigator's signature

_____

Date

*Companies include: Genentech, Inc., CIBA-GEIGY Corporation, Marion Laboratories, Inc., SmithKline Pharmaceuticals, and Mallinkrodt, Inc.

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