Thoracic Surgery Outcomes Research Network (ThORN)

CONSTITUTION/BYLAWS

MISSION STATEMENT

The mission of the **Thoracic Surgery Outcomes Research Network (ThORN)** is to increase evidence based understanding, advances and education in health services/outcomes research within the general thoracic surgery specialty by a multi-institutional cooperative of faculty, trainees and other stakeholders.

ARTICLE I - NAME

The name of this organization is: ThORN. Hereinafter referred to as "the Group."

ARTICLE II - PURPOSES

The Group is a cooperative amongst multi-institution faculty, trainees and staff whose research interests include outcomes/health services research. The goals of the Group are to:

- Provide a forum for the sharing of ideas
- Facilitate networking among general thoracic surgical researchers
- Create grass roots health services research infrastructure within the cooperative
- Help develop outcomes research leaders.
- Develop multispecialty research protocols and projects

Surgical Health Services/Outcomes Research includes, but is not limited to scholarly investigations of:

- Quality Measurement and Improvement
- Collaborative Quality Improvement
- Cost effectiveness and efficiency
- Healthcare Disparities
- Healthcare Entrepreneurialism
- Healthcare Policy
- Patient-Centered Outcomes Research
- Comparative Effectiveness Research
- Dissemination and Implementation
- Clinical Trials

ARTICLE III - MEMBERSHIP

SECTION 1 - INDIVIDUAL MEMBERSHIP

A. MEMBERS are surgeons, scientists, trainees and staff, with clinical and/or research

interests in the surgical treatment of thoracic disease, who participate in the scientific and/or administrative conduct of Group studies at a Member Institution. No limitation shall be made on the number of Members. Potential members are reviewed by the Executive Committee and must be approved by a simple majority. Individuals interested in becoming members need to provide their names, appointment information, contact information and a brief statement of research interests.

Members have the following privileges:

- Participation in monthly and ad hoc meetings including conference calls and regional meetings, didactics and research presentations
- Participation in protocol design
- Registration and assessment of subjects on appropriate Group protocols
- Coordination and publication of collaborative research efforts
- Election or appointment to any position and/or any Committee of the Group

B. AFFILIATE PROGRAM MEMBERS are individuals who participate in the scientific and/or administrative conduct of Group studies at an Affiliate of a Member Institution. No limitation shall be made on the number of members at any Affiliate. These individuals are reviewed by the Executive Committee and must be approved by a simple majority vote. Individuals interested in becoming affiliate program members need to provide their names, appointment information, contact information and a brief statement of research interests.

Affiliate Members have the following privileges:

- Participation in monthly and ad hoc meetings including conference calls and regional meetings, didactics and research presentations
- Participation in protocol design
- Registration and assessment of subjects on appropriate Group protocols
- Coordination and publication of collaborative research efforts

C. SPECIAL MEMBERS are individuals who have special expertise not thought to be available among the Member Institutions. They are reviewed by the Executive Committee and must be approved by a simple majority vote. Individuals interested in becoming special members need to provide their names, appointment information, contact information and a brief statement of research interests. Privileges of the Special Member will be determined by the same mechanism.

SECTION 2 - SUSPENSION AND REVOCATION OF MEMBERSHIP

A. AFFILIATE PROGRAM MEMBERSHIP can be terminated at any time by a simple majority vote of the Executive Committee.

B. INDIVIDUAL MEMBERSHIP is terminated by a simple majority vote of the executive committee or by a letter of resignation from an individual member. Individual

Membership may be revoked for cause upon the recommendation of the Executive Committee.

ARTICLE IV – EXECUTIVE COMMITTEE AND OFFICERS

SECTION 1 – EXECUTIVE COMMITTEE is the governing body of the Group. The Executive Committee shall consist of the following:

1. Chair
2. Vice-Chair
3. Past-Chair
4. Secretary
5. Treasurer
6. Councilors at Large x 4

Terms of Office

Officers of the Group shall each hold offices for two years or until their successors are duly elected by the Executive Committee. There will be an automatic line of succession from Past-Chair, Chair, Vice-Chair and Secretary. The Chair, at the end of a two-year term, shall automatically, and without vote, continue as an officer for a two-year term as Past-Chair; the Vice-Chair shall automatically, without vote, succeed the Chair, and the Secretary shall automatically, and without vote, continue on as Vice-Chair. After the Secretary has moved onto the position of Vice-Chair, an election shall be held to fill the Secretary position. The Treasurer shall be voted upon every two years, and is exempt from the automatic line of succession.

If the office of the Chair becomes vacant by reason of death, resignation, retirement, disqualification, and removal from office or otherwise, the Vice-Chair shall become Chair, fill the remainder of the unexpired term, and then continue on as Past-Chair. Such unexpected progression of the Vice-Chair to the office of the Chair shall result in the Secretary advancing to Vice Chair, and special election of a new Secretary by the Executive Committee within one month of the vacancy of the Chair office. Such successor(s) shall hold office for the unexpired term with respect to the vacancy occurring.

Duties of Officers

Chair: The Chair shall preside at all meetings of the Group membership and at all meetings of the Executive Committee; and shall perform all duties usually associated with the office of the Chair, including the appointment of various committees as directed by the Executive Committee and/or the assembled members at regular meetings of the Group. The Chair shall be responsible for the regularly scheduled Group meetings; and shall be a member or ex-officio member without vote on all committees. Affiliate and Special Members are not eligible to serve as Chair. The Chair's vote will serve as a

deciding vote in case of an Executive Committee voting tie.

Vice-Chair: The Vice-Chair shall chair and manage the Nominating Committee. If the Chair is absent or unable to act, the Vice-Chair will perform the duties and exercise the powers of the Chair; and will assist the Chair in any capacity necessary. Affiliate and Special Members are not eligible to serve as Vice-Chair. The Vice-Chair's vote will serve as a deciding vote in case of an Executive Committee voting tie and the Chair is absent.

Past-Chair: The Past-Chair shall work with the Chair and the Executive Committee to assure uninterrupted assumption of assigned duties; shall attend regularly scheduled Group meetings; shall assist the Chair in all capacities necessary; The Past-Chair will be a voting member of the Executive Committee.

Secretary: The Secretary shall prepare and distribute minutes of all meetings of the Group; shall maintain the records of the Group including a list of all members, including the Executive Committee members and subcommittee representation; and shall be responsible for maintaining an up- to-date website. Affiliate and Special Members are not eligible to serve as Secretary. The Secretary will be a voting member of the Executive Committee.

Treasurer: The Treasurer will also be responsible for presenting and maintaining the record of a budget. The Treasurer will also be responsible for identifying extramural funding opportunities for the Group. Affiliate and Special Members are not eligible to serve as Treasurer. The Treasurer will be a voting member of the Executive Committee.

Counselor-at-Large: A Counselor-at-Large shall attend regularly scheduled Group meetings; shall assist the Chair in all capacities necessary; shall provide general insight and expertise for the Group. Counselors-at-Large will be voting members of the Executive Committee. Affiliate and Special Members are eligible to serve as Counselor-at-Large. Thoracic trainees are eligible to serve as Counselor-at-Large. Only one of the four Counselors-at-Large can be a trainee. Counselor-at-Large positions are two year elected positions. Term limits are limited to two full terms. Individuals can be voted into additional Counselor-at-Large terms as long as an additional term is not in succession with two served terms.

A vote of "no confidence" can be proposed by any member of the executive committee on a quarterly basis to terminate the term of a member of the executive committee. This shall result in a vote by the other members of the executive committee excluding the subject of the vote of "no confidence" and be decided by a two thirds majority. If the vote of "no confidence" results in decision to terminate the term of a member of the executive committee, then that position shall be vacated at the end of the ongoing quarter. A subsequent election will be held within the following quarter to fill the vacancy, per the voting guidelines outlined in these Bylaws.

Section 2:
Committees and Task-Forces

Nominating Committee
The Executive Committee will also serve simultaneously as the Nominating Committee and shall be responsible for identifying upcoming vacancies in the Executive Committee and soliciting nominations for the vacancy. The open positions will be emailed to the membership and posted on the Group website for one month during which time any member can be nominated either by themselves or another member. A brief statement of intention from the nominee must accompany all nominations, which will be distributed to membership prior to voting. To be eligible for the Executive Committee, the nominee must be a board-eligible or board-certified thoracic surgeon, who is a founding member, or who has been an individual member for at least one year and in good standing.

The first Nominating Committee will be the founding members of the Group. After the first Executive Committee has been finalized, and these Bylaws ratified, all subsequent Nominating Committees will follow the rules outlined in these Bylaws.

The members of the Nominating Committee shall consist of the Vice-Chair who will chair the committee, the Past- Chair, and two at large members. The Nominating Committee will receive and review all nominations and present the nominations to the Executive Committee for a final vote. A new Executive Committee member is then elected by majority vote of the seated Executive Committee. A final decision in the circumstance of a tie will be made at the discretion of the Chair.

Executive Committee
The Executive Committee will consist of 8-9 voting members (9 once there is a Past-Chair). The Executive Committee shall generally manage the affairs of the Group and shall serve as the administrative and policymaking body of the Group. A majority of the Executive Committee shall constitute a quorum for the transaction of business. Meetings of the Executive Committee shall be held at least quarterly and ad hoc, or at such times and places as may be agreed upon by a majority of the Executive Committee, or in the event of disagreement, as designated by the Chair. Some correspondences and voting sessions of the Executive Committee may be performed electronically such as by email. Members of the Executive Committee shall include the Past-Chair, the Chair, the Vice-Chair, the Secretary, the Treasurer and the Counselors-at-Large.

Standing Committees
The Executive Committee establishes standing Committees for a period of up to five years. To continue beyond the five-year period, the committee(s) must be reestablished by vote of the Executive Committee. They may be abolished at any time by similar vote. They shall perform such duties and functions as assigned by the Chair of the Executive Committee. All standing committees shall be composed of at least four members appointed by the Chair, subject to approval of the Executive Committee. Approximately one-third of the members of each committee shall be appointed annually and will not have a term limit.

Although Chairpersons and members of standing committees are appointed for

terms of specific duration, any incoming Chair may, at the beginning of his/her Presidency, conclude the service of any Committee Chairperson or member after the first year of his/her term and appoint a new Committee Chairperson or Committee Member subject to the approval of the Executive Committee. The Chair will appoint the chairpersons of these committees. They will report the actions of their committees to the Executive Committee and the Group at regular meetings of these bodies.

D. AD HOC TASK-FORCES shall be temporary committees established as necessary to accomplish a specific task. The Ad Hoc Committee Chair and members shall be appointed by the Group Chair and serve at his/her pleasure.

ARTICLE V - MEETINGS
Group Meetings are the regularly scheduled monthly conference call meetings attended by the members and associated members from all disciplines as well as in person ad hoc meetings. Interim Meetings are meetings or didactics called at the discretion of the Executive Committee or the Group Chair.

ARTICLE VI - QUORUM
Quorum for the Executive Committee is fifty percent presence or electronic response.

SECTION 1 – BYLAWS/POLICIES
Bylaws, as are deemed necessary for the efficient and effective operation of the Group, may be adopted by a simple majority vote at a regularly scheduled meeting of the Group. The vote may be performed electronically.

SECTION 2 - AMENDMENTS
Amendments, additions or deletions to this Constitution must be proposed by a Member and seconded by another Member. The proposed amendment shall be circulated to the Executive Committee. Approval shall require a two-thirds majority vote of the executive committee, which may be any mechanism (email vote, special meeting or regularly scheduled Group Meeting) at the discretion of the Group Chair. Votes to ratify amendments may be performed quarterly.

SECTION 3 - RATIFICATION
This Constitution shall be adopted upon its approval by a simple majority of the Group, and shall become effective immediately after its adoption. Upon ratification, it shall supersede any previous document serving this purpose.

SECTION 4 - PARLIAMENTARY PROCEDURE
All proceedings at the Meetings of the Group and any questions of order not provided for by the Constitution and the most recent edition of Newly Revised Robert's Rules of Order governs Bylaws, except where otherwise provided. The Executive Committee will take advantage of the option to use a Consent Agenda. A "Consent Agenda" is a grouping of non-controversial agenda items that are expected to be approved without discussion. Routine items will be grouped together on the agenda with a heading of "Consent Agenda." When the Executive Committee reaches that portion of the agenda, the Chair will ask if any member wishes to remove (or pull) any item from the consent agenda.

Pulling an item does not require a second. After all the "pulls" are made, the Chair states, "Without objection, the remaining items (or all the items if none have been pulled) are adopted by general consent." If any member wants to discuss or vote on an item separately, he/she must pull it from the consent agenda. If any items are pulled, the board can either take them up immediately for discussion and vote or put them in their appropriate place in the agenda.

GROUP COMMITTEES**

Research Committees
Topical research committees focused on areas of surgical health services/outcomes research scholarship may be established at the discretion of the Executive Committee.

Biostatistics Committee
The Biostatistics Committees support high-quality clinical and outcomes research efforts within the Group. The biostatistics committees work closely with surgeon-investigators to understand the clinical background of projects help refine proposed analyses, conduct analyses, and help describe and interpret the analyses for presentation. The committees will be established at the discretion of the Executive Committee.

ADMINISTRATIVE COMMITTEES
Nominations Committee

** Committees are subject to revision, addition, change, etc., per applicable Bylaws

AUTHORSHIP

1.0 BACKGROUND

Publication of the results of collaborative ThORN research endeavors is important in meeting the Group's mission. The following describes the Group's Authorship Policies and includes general themes that apply to all ThORN activities. While the specifics described are intended to address most the Group's activities, supplemental documents may be developed for special programs and circumstances.

ThORN supports and subscribes to the policies of the International Committee of Medical Journal Editors' Uniform Requirements for Manuscripts Submitted to Biomedical Journals (http://www.icmje.org/). These Requirements state "Authorship credit should be based on 1) substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data; 2) drafting the article or revising it critically for important intellectual content; and 3) final approval of the version to be published. Authors should meet conditions 1, 2, and 3." For the purposes of reporting results of studies, the Group will consider substantial contributions to subject accrual as meeting criterion 1), as accrual has important implications for the "acquisition of data".

2.0 CATEGORIES OF AUTHORSHIP

The following describes normal procedures for identifying authorship for ThORN projects and emphasizes the reporting of Primary Analyses of studies. As roles may change over the conduct of a study, the principles and policies described below may require study-specific interpretation and application. When specific extramural studies conducted in conjunction with other agencies require authorship polices that deviate from those described in this document, negotiation of the policies should occur prior to finalizing the protocol and should be included in the protocol.

The stated parameters are contingent upon individuals meeting the requirements listed below, those described by the International Committee of Medical Journal Editors (see Section 1.0 above), and completing NCIC CTG Conflict of Interest requirements in an acceptable manner. These parameters are based on the expectation that following the availability of a final analysis, the results of a project will be presented at a scientific meeting within 6-12 months, a first draft of an article manuscript will be completed within 6 months, and the final manuscript will be submitted to a medical journal within 12 months. Failure to meet any of the above requirements may lead to revisions in authorship and authorship position.

In general, authors will be named as individuals with as many authors included as permitted by the intended journal. Situations may exist where it is more appropriate to have authors named under an umbrella term. In these situations, a Writing Committee will be named and will include members of the Trial Committee.

2.1 First Author

The First Author is the designated leader of the project. This position should be named at the beginning of the project. For clinical trials, the first author will be the Study Chair. For trials with co-chairs, options will include having the co-chairs included as the first and second authors, as co-first authors as designated with an asterisk, or with one co-chair as Senior Author.

Requirements for First Authorship include:

- Leading the process to design the research (trial)
- Actively participating in the project's conduct throughout the life of the project
- Leading the representation of the project at national and international meetings
- Participating in the analysis of data; and,
- Taking direct responsibility to produce a manuscript.

A requirement of First Authorship for clinical trials is that the investigator has actively and directly participated in trial accrual.

2.2 Senior Author

The Senior (last) Author is an investigator who has played a central role in the specifics of the project and who also has had a major role in the development and oversight of the program on which the project is based.

Requirements for Senior Authorship include:

- A leadership role in designing the research (trial)
- Actively participating in the project's conduct throughout the life of the project
- Leading the representation of the project at national and international meetings; and,
- Participating in the analysis of data and overseeing the processes to produce a manuscript

When the Senior Author is based at an NCIC CTG member center, a requirement of Senior Authorship for reports of clinical trials is that the investigator has actively and directly participated in trial accrual.

For the Primary Analysis of a trial, providing that the above requirements are met, the Senior Author will generally be a Site Chair. However, the life span of many trials is such that sustained leadership by Site Chair is not always possible, or instances may occur where the Central Coordinator or a member of the Trial Committee has more fully met the requirements; under these circumstances, one of these individuals will be the Senior Author.

2.3 Second Author

In general, the principles for naming a Second Author will follow those for naming of the Senior Author. For the Primary Analysis of a trial, the Second Author will generally be the Central Coordinator. When it is more appropriate that the Physician Coordinator be named as the Senior Author, the Second Author will either be the Study Co-chair, or the individual who has otherwise best met the criteria of:

- Participating in designing the research (trial)
- Actively participating in the project's conduct throughout the life of the project
- Leading the representation of the project at national and international meetings; and,
- Participating in the analysis of data and the writing of the manuscript

2.4 Third Author

The principles for naming a Third Author include those described for the naming of the Senior and Second Author. In addition, for collaborative studies with other organizations, the Third Author will be the designate from the group that has accrued the most patients, provided that this total is at least 25% of all accrual and this group has:

- Contributed to the design of the research (trial);
- Actively participated in the project's conduct throughout the life of the project;
- Led the representation of the project at respective national and international meetings; and,
- Participated in the analysis of data and processes to produce a manuscript.

When the Third Author is based at a ThORN member institution, contributions to accrual will be an important criterion for selection.

2.5 Co-Senior (Second Last) Author

For the reporting of Primary Analyses the second last author position represents co-senior authorship. In circumstances where a biostatistician is principally involved in the construction, data accrual and analysis of the study, this individual may occupy this authorship position such that the importance of the statistical contribution may be appropriately recognized.

2.6 Other Contributing Authors

Other authorship positions will be based on contributions to the conduct of the project (trial). The following principles will be used to name and to determine the order of these authors:

i. Investigators based at ThORN institutions who are members of the
ii. Trial Committee will be included provided that these individuals have actively participated in the project's conduct throughout the life of the project, including making contributions to accrual.
iii. For Intergroup trials, a member of a cooperative group that has contributed at least 5% to the total accrual will be included. An additional member from that group will be included for each additional increase of 10% to the total accrual (i.e. 2 authors for > 15%, 3 authors for > 25%, etc). Each cooperative group will be asked to identify the author(s) to be named.
iv. Additional authorship positions will be determined by member institution accrual. In general, an investigator from each of the highest accruing centers that are not otherwise represented with authorship will be identified. The responsibility for identifying this investigator rests with the participating institution. The Central Office will provide that center's Principal Investigator with the Central Office's attribution of that center's accrual so that the Principal Investigator can identify the appropriate author. If there are disputes in identifying this individual, the study's Principle Investigator will contact the Center Representative and request that he/she mediate a decision.
v. When a center has contributed a disproportionately large percentage of accrual, additional authors from that center may be selected.
vi. For research conducted with an industry collaborator, a representative of the company may be included when the nature of the collaboration is associated with meeting the criteria stated in Section 1.0 above.

2.7 Acknowledgements

Where journal policies permit; all investigators who played a contributing role in the trial, including to its accrual, will be included in an Acknowledgement section. The Executive Committee with direct project-specific responsibilities will also be acknowledged.

Acknowledgements of funding support are described in *Policies for Publication: Policy Overview*. Publications, presentations and products (henceforth termed "publications") emanating from ThORN-originated and directed research must include formal acknowledgement of "ThORN – Thoracic Outcomes Research Network". Participants will be subject to expulsion from ThORN should they publish under the name of ThORN without proper approval, or utilize ThORN resources without crediting ThORN.

2.8 Approval of Publications

All ThORN publications must be reviewed by members of the Executive Committee in a timely manner so as not to delay intended submission or application. A two-thirds majority of the Executive Committee will be needed to approve a publication. It will review and approve all written materials to be submitted for publication (either in peer-reviewed journals, on-line sources, or other media), technical documentation to be shared with members or outside organizations, and public relations products sent to news media for the general public. The Executive Committee will make decisions regarding authorship and other editorial functions.

3.0 POLICIES ASSOCIATED WITH NON-PRIMARY ANALYSIS PUBLICATIONS

Other types of analyses are described in Section 2.2 of *Policies for Publication: Policy Overview* and include Planned Secondary Analyses, Unplanned Secondary Analyses, Meta-analyses, and Methodologic and Related Research. Principles for naming authors to these manuscripts include:

3.1.2 Respect of Leadership: ThORN supports the leadership roles played by the Study Chair, the Site Chair, the Physician Coordinator and the Senior Biostatistician. Provided that each has participated in a manner consistent with the principles of authorship described in Sections 1 and 2 above, these investigators would be expected to be co-authors of manuscripts reporting the results of a project resulting in a non-primary analysis publication.

The Group further respects the leadership roles of designated leaders who are Trial Committee members. In this context, these investigators are expected to be the First Author of publications related to the reporting of secondary outcomes associated with the role these individuals play on a Study Committee.

3.1.2 Respect of Concept Ownership: ThORN respects the need to recognize the originator of a concept. In general, the originator of a concept will be provided with the opportunity to meet the additional criteria that result in being named First Author.

3.1.3 Respect of Group Principles: The nature of a cooperative group requires that collaborations be nurtured. The most prestigious of authorship positions

(First Author, Senior Author) must therefore be appropriately distributed among the individuals eligible for these positions across the reports associated with a project. Similarly, positions of Other Contributing Authors should be distributed to account for contributions to a project, including trial accrual.

3.1.4 Promotion of New Investigators: The training and promotion of new investigators is a stated strategic priority of the Group. Opportunities to engage new investigators, particularly in forms of non-primary analyses, should be considered.

3.2 Specific Policies

3.2.1 Authorship for Intergroup Trials Led by Other Groups: It is expected the ThORN Study Co-chair will be designated as the author for Intergroup trials led by other groups. This should be discussed with the lead group at the outset of the trial. It is expected that the requirements for authorship will be consistent with ThORN policies for authorship and include:

- Actively participating in the project's conduct throughout the life of the project (including actively and directly participated in trial accrual)
- Leading the representation of the project at national meetings; and,
- Participating in the analysis of data and the processes to produce a manuscript

When ThORN institutions have entered more than 15% of all patients accrued, the Group will enter into discussions with the lead group about naming additional authors.
When an Intergroup-led project results in multiple reports, ThORN will perform a review of trial conduct, including accrual, to ensure that Group principles (Section 3.1.3 above) are respected. A process to identify a sequence for naming deserving authors will be developed by the Physician Coordinator in conjunction with the Site Chair and the Study Co-chair.

3.2.2 Authorship on Meta-analyses: Meta-analyses are complex collaborations and, given the large number of potential collaborating groups, opportunities for authorship from a single group, such as ThORN, may be limited. To be a candidate for authorship, an investigator must have played a substantial role in each of the criteria for authorship listed in Section 1.0 above.

Furthermore, the potential author must play a participating role in the meta-analysis collaboration. When there are multiple candidates for authorship, a process to identify a sequence for naming deserving authors will be developed by the Physician Coordinator in conjunction with the Site Chair, the Study Co-chair and the (if involved) Senior Biostatistician.

4.0 DISPUTE RESOLUTION

The responsibility for initiating resolution of disputes in authorship rests with the Executive Committee. When disputes involve identifying the contributing author from a high-accruing center, the Vice-Chair will contact that center's Center

Representative to request that he/she mediate a decision. In circumstances where the above processes do not resolve an authorship issue, the ThORN Vice-Chair has ultimate responsibility for mediating a resolution and / or determining a final naming of authors. Where applicable, the Chair may choose to form an *ad hoc* subcommittee from the Executive Committee to help arbitrate a conclusion.

RESEARCH PROPOSALS

1.0 BACKGROUND

Research proposals submitted to the ThORN Executive Committee for consideration and constructive feedback are important to conducting quality collaborative research studies. The following describes the Group's policies with regards to research proposals and outlines the procedure for submitting them.

The ThORN research proposal form is to be completed for all types of research studies planning on using the Group's database and/or prospectively collected data. ThORN research proposal forms will be accepted and reviewed by the Executive Committee on a quarterly basis (Jan 1st, April 1st, July 1st, Oct 1st of each year) or sooner if directed by the Chair or Vice-Chair. There will be an appropriate period of comment prior to formal vote on the proposal, open to the Executive Committee. Research proposals can move forward after receiving a simple majority vote from Executive Committee. Applications for extramural funding after Executive Committee voting approval, can receive a letter of support from the Chair or Vice-Chair.

2.0 RETROSPECTIVE STUDIES

Retrospective studies include those studies that can be completed via use of the Group's database. The ThORN research proposal form is to be submitted to the Executive Committee. The research proposal must include a statistical analysis plan including collaboration with a biostatistician. The Executive Committee will review each research proposal and vote in favor or against it. In addition to the vote, the voting member may include constructive criticism with the aim of improving upon the submitted research proposal. Research proposal applicants will be informed of whether the proposal was approved within 4 weeks of submission. Approved research proposals will be granted access to the database to complete the proposed study.

3.0 PROSPECTIVE STUDIES

Prospective studies include observational cohort studies and randomized controlled trials. The ThORN research proposal form is to be submitted to the Executive Committee. The research proposal must include a statistical analysis plan including collaboration with a biostatistician; all randomized controlled trials must include a power analysis. The entire Group will review each proposal and all Member Institutions interested in participating are to contact the Principal Investigator within 4 weeks.

4.0 GRANTS AND FUNDING

Principal Investigators whose research proposal has been approved may then apply for grants and other sources of funding. If the Principal Investigator receives a grant or any other funding, the funds are to be used at the discretion of the Principal Investigator.