Duke University Cooperative Cardiovascular Society (DUCCS)

The Duke University Cooperative Cardiovascular Society, DUCCS, is a society of current and past Duke Faculty members and fellows of Duke's Cardiovascular Diseases Training Program; and member-sponsored clinical educators and investigators. DUCCS is based within the Duke University Medical Center Heart Center, and Department of Medicine, Division of Cardiology. The purpose of DUCCS is to enhance the professional careers of its members through collaborative efforts in cardiovascular research and continuing education.

DUCCS supports the scholarly interests of its members by providing research and educational programs. (Appendix 1) DUCCS also serves as a resource for fellows graduating from Duke Cardiovascular Fellowship Training who are interested in developing their own clinical research and/or education programs.

DUCCS GOVERNANCE

DUCCS Board of Directors

DUCCS is governed by a Board of Directors which is comprised of the following members: two elected officers (President and Vice President) and eight at large or general DUCCS board members nominated by active members and selected by the Executive Committee of the Board. The remaining members of the board consist of two Duke Faculty liaisons, one Duke Fellow Liaison, one clinical research coordinator (DUCCSinator), the DUCCS Immediate Past President, the DUCCS Director and the Administrative Director. The Board of Directors will meet bi-monthly by conference call, and face-to-face once each year at the national scientific meetings of the American College of Cardiology. Additional meetings can be scheduled with reasonable advance notice at the discretion of the President. The Board will announce at the time of the annual AHA meeting the number of positions open for the following year.

Nominations for the General Board positions will be made by the Active members. The Executive Committee of the board will elect the new board members. The new members will be notified in late January and announced prior to the annual ACC meeting.

DUCCS Officers and Executive Committee

The two officers of the Board of Directors are elected by the DUCCS Active Members. Current members of the Board of Directors and those who rotated off the board within 3 years of the election are eligible for the offices of President and Vice President. These officers and the DUCCS Director will form the Executive Committee of the Board.

DUCCS General Board Members

The general board members will serve a three year term beginning at the annual meeting of ACC. The three year terms of the General Board members will be staggered so that there are two or three new General Members elected each year.

A Board Member who retires or is inactive can be removed and replaced by 3/4 vote of the full Board.

DUCCS Standing Committees

The DUCCS Executive Committee will appoint active DUCCS members to the Standing Committees for a one year term; and identify a DUCCS board member to serve as chair for each committee. The Standing Committees of the Board are:

- Finance
- Membership
- Research
- Education

DUCCS Director

This will be the funded member of the Duke Cardiology Faculty. The Director will be nominated by the Chief of Cardiology and approved by the DUCCS Board. The Director will serve 3 year terms, with re-nomination and re-approval required at the end of each term.

DUCCS Administrative Director

This position is filled by appointment by the Board for an indefinite term (re-assessed annually). The DUCCS Administrative Director is a non-voting member of the Board.

Duke Faculty and Fellow Liaisons

The two Duke Faculty Liaisons serving as liaisons with the Duke Heart Center/Duke Cardiovascular Division will appointed by the Duke Chief of Cardiology and approved by the Board. The length of terms of the Duke Faculty liaisons is three years, with a limit of three consecutive terms.

One Duke Cardiology Fellow liaison will be appointed by the DUCCS Director and the two Duke Cardiology Faculty liaisons and approved by the Director of the Duke Cardiology Training Program. The term of the Duke Cardiology Fellow liaison will be one year with a term limit to be set at two consecutive terms.

DUCCSinator

The DUCCSinator member of the Board is nominated and elected by DUCCSinators in collaboration with the DUCCS Board of Directors and approved by the members of the Board of Directors. The term of the DUCCSinator will be three years, with a limit set of two consecutive terms.

DUCCS Elections

Elections of a new President will take place every three years. All Active DUCCS members are eligible to vote for officers. The person receiving the 2nd highest number of votes will serve as Vice-President. The DUCCS President and Vice President can serve no more than two consecutive three-year terms within each position. They, along with the Director, form the Executive Committee.

Voting for the DUCCS officers by the active members from among the nominees will be conducted in January. Announcement of new board members will be made mid to late-January and new terms will begin at the annual scientific meeting of the American College of Cardiology. After the completion of his/her term as President, the Immediate Past-President will serve as a voting member of the Board for a term of three years.

DUCCS BOARD MEMBERS RESPONSIBILITIES

DUCCS President

- Sets the agenda and chairs all Board of Directors meetings. Board of Directors conference calls and annual meetings will be conducted according to Robert's Rules of Order.
- 2. Helps to identify and recruit new sites working with DUCCS Director, Duke Faculty liaisons and Duke Fellowship Director.
- 3. Solicits industry initiated studies, and helps negotiate contracts for DUCCS members.
- 4. Develops collaborative ties with other clinical research organizations and various academic institutions.
- 5. Facilitates member-initiated studies.
- 6. Helps solicit continued funding for DUCCS from grants and industry.
- 7. Appoints ad hoc subcommittees, examples, newsletter committee, website committee; global/international site committees.
- 8. Serves as a member of all committees and subcommittees.
- 9. Works with Chief of Cardiovascular Division and Director of the Duke Heart Center in identifying opportunities for gifts on behalf of the DUCCS organization.
- 10. Establishes SOPs for guidance of the DUCCS Administrative Director.
- 11. Reviews and finalizes all DUCCS documents, including meeting minutes and newsletters.
- 12. Reviews all proposed research grants for the DUCCS network and provides a summary to the Board.

DUCCS Vice President

- 1. Carries out all of the duties of the President in the absence of the President.
- 2. Works with DUCCS staff to publish a quarterly newsletter.
- 3. Helps solicit for continued funding for DUCCS from grants and industry.
- 4. Has responsibility for membership initiatives.
- Provides opportunities for current Duke Cardiology fellows to become future DUCCS members.
- 6. Oversees the Society's revenues and expenses.
- 7. Helps prepare the Society's annual report for submission to the Board of Directors and to the full DUCCS membership at its annual meeting.

DUCCS General Board Member

- 1. Is a voting member.
- 2. Participates in the board calls.
- 3. Participates in committees as delegated by the DUCCS President.
- 4. Participates in other DUCCS activities as delegated by the DUCCS President.
- 5. Must attend 2/3 of scheduled board meetings annually to retain his/her board position.

DUCCSINATOR Representative

- 1. Represents the DUCCSinators on the Board of Directors.
- 2. Serves no more than two consecutive three-year terms.

NETWORK ADMINISTRATION

DUCCS ADMINISTRATIVE OFFICE

The DUCCS Duke Administrative Office includes the DUCCS Director, the DUCCS Administrative Director, the senior and junior Duke Faculty liaisons and the fellow liaison. They form the primary link between the DUCCS members and the Duke Heart Center/Cardiovascular Division. Funding for this office is the responsibility of the DUCCS organization.

DUCCS Director

- 1. Spends at least a half day per week in the DUCCS office.
- 2. All Responsibilities of Duke Faculty Liaisons.
- 3. Assurance of stable DUCCS organization by direction of all aspects of DUCCS.
- 4. Supervise the DUCCS administrative staff.
- 5. Oversee membership.
- 6. Has primary financial responsibility and facilitates all of the business activities of DUCCS.
- 7. Serves on the Executive Board.
- 8. Signs for DUCCS on appropriate Duke documents, forms and contracts.
- 9. Funded by Duke Cardiology Division, offset by DUCCS endowment.
- Delegate minor operational expenditures to the Administrative Director.

DUCCS Administrative Director

- 1. Is a non-voting member of the Board.
- Works under the direction of the DUCCS Director and is responsible for the day to day operations of DUCCS.
- Assists the DUCCS Director with planning, coordination and implementation of DUCCS business.
- 4. Tracks and reports finances to the DUCCS Executive Committee.
- 5. Coordinates communication among Board members and the faculty liaisons.
- 6. Coordinates communication from the Board to DUCCS members and the faculty liaisons.
- 7. Plans, coordinates and implements DUCCS activities.
- Establishes and maintains contact with the Duke University Fellows Society and DUCCS members.
- Maintains the database of DUCCS members. Updates the cardiology fellowship database as necessary.
- 10. Maintains the DUCCS website.
- 11. Plans, implements and facilitates communication with the DUCCSinators.
- 12. Makes arrangements for all DUCCS meetings.
- 13. Arranges for speakers, collects meeting materials and attends DUCCS meetings.
- 14. Facilitates the Board's monthly calls, collects and posts pertinent information to the DUCCS website.
- 15. Plans, implements and participates in conference calls with principal investigators, study champions and DUCCSinators for all on-going DUCCS trials/studies.
- 16. Tracks DUCCS member/site progress on DUCCS studies, generates reports, distributes to Board, posts on website.
- 17. Will follow DUCCS SOPs as established.

Duke Faculty Liaisons

- 1. Represent Duke Heart Center and Duke Division of Cardiology on the Board of Directors.
- Work with President and Vice-President to help them meet their responsibilities and achieve their goals.

- Work with Duke Faculty to identify potential DUCCS investigators and new sites for projects.
- 4. Identify Duke Fellows to work with DUCCS ongoing projects.
- 5. Help identify and recruit new DUCCS sites by working with Duke Fellowship Director.
- 6. Solicit industry-initiated studies and help negotiate contracts for DUCCS members.
- 7. Develop collaborative ties with other clinical research organizations and various academic institutions in collaboration with the DUCCS Board
- 8. Facilitate member-initiated studies.

Duke Fellow Liaisons

- 1. Represent Duke Cardiology Fellows on the Board of Directors.
- 2. Work with President and Vice-President to help them meet their responsibilities and achieve their goals.
- 3. Work with Duke Fellows and Duke Cardiology Fellowship Director to promote DUCCS within the fellowship program.
- Assist DUCCS Faculty Liaison to identify Duke Fellows to work with DUCCS ongoing projects.
- 5. Help identify and recruit new DUCCS sites by working with Duke Fellowship Director.
- 6. Facilitate member-initiated studies within Duke.

Duke Chief of Cardiovascular Division

- Approves the DUCCS Board of Director's appointments of the Duke faculty liaisons and Director of DUCCS.
- Meets bi-monthly with the DUCCS Director, Administrative Director and Duke Faculty liaisons.
- 3. Invited to join the monthly Board conference calls.
- 4. Promotes DUCCS within the Division, encourages active participation.

DUCCS MEMBERSHIP

Active membership status will be considered for cardiologists who trained at Duke, former Duke Cardiology Faculty or those nominated by a member of the Board who knows them to be excellent physicians with competence and experience that will add value to the DUCCS organization. DUCCS members are classified as being Active; Inactive or Emeritus. Active DUCCS Membership status is achieved by payment of annual DUCCS dues – to be determined yearly at the national meeting.

Members who have contributed more than \$3000 to DUCCS through membership or endowment will be recognized as Sustaining DUCCS Member. Although requests for active membership dues will be made to Sustaining members, they will be considered active members after reaching sustaining member.

Current Cardiology Fellows are considered inactive members until they express formal interest to the Fellow Liaison in being an active DUCCS member. Annual membership dues are waived during fellowship. For the first two years after training, annual dues rates are reduced to a level determined by the DUCCS board. Subsequent year's dues revert to the annual renewal rate.

Current or past Duke Faculty members or fellows in Duke's cardiovascular training program are eligible to be Active Members.

Individuals who have not been a Duke Faculty member or fellow can be sponsored by an active DUCCS Member and can become an Active member with the approval of the Board of Directors.

A DUCCS member can have his/her membership terminated because of professional misconduct with the forfeiture of his/her membership dues and fees by a 3/4 vote of the Board of Directors after being given written due notice, and the opportunity to appeal to the DUCCS Board of Directors. The dismissal will be reversed by a simple majority of the Board.

BENEFITS OF DUCCS MEMBERSHIP

Benefits of DUCCS Membership as well as a Menu of Services are outlined in Appendix 1. The Appendix can be approved by simple majority of the board vote and does not require a constitutional amendment.

DUCCS SITES

A DUCCS Site will be the primary cardiology practice site of an Active DUCCS member. Each site will have an Active DUCCS member designated as "DUCCS Site PI", responsible for sponsoring others from that site as DUCCS Active Members. The Duke Cardiology Fellows will also be considered a DUCCS Site, and PI will be the DUCCS Fellow Liaison.

Selected DUCCS Sites will be characterized as a "High Performing Site" and will be given priority for DUCCS clinical trial participation. Criteria for a high performing site include:

- 1. the origination of a DUCCS sponsored clinical trial;
- 2. Being a top five DUCCS enroller in one or more of the DUCCS sponsored clinical trials over the past three years., and/or
- 3. Top 25% US enroller in the multi-center clinical trial or registry that is registered with the FDA.

When a DUCCS member retires or leaves his/her site while a DUCCS sponsored clinical trial is in progress, the DUCCS member can sponsor a colleague at the site to assume responsibility for the on-going clinical trial. Approval by the DUCCS Board of Directors is required for a non-DUCCS member. When a DUCCS member retires or relocates from an Inactive DUCCS Site, the aforementioned nominating process will be required to designate a new DUCCS member at that site.

For DUCCS sites that fail to maintain the minimal standards for clinical research performance, the Board will vote on whether to allow them to continue enrolling in the clinical trial under the DUCCS status. This can only be done after a warning has been given in writing to the DUCCS member. If the Board votes (simple majority) for the site to be discontinued from DUCCS status for that specific trial, the membership status is not jeopardized. The DUCCS Board has the authority to invite and not invite any DUCCS member to participate in a specific clinical trial.

DUCCS sites can also be categorized as "probationary". Probationary Sites are defined as sites with:

- 1. a single major protocol violation
- 2. enrollment numbers in the bottom 25% of US sites
- 3. a high dropout or lost to follow up rates
- 4. multiple minor protocol violations

5. poor performance in completing case report forms and query responses

DUCCS CHAMPION

Each DUCCS initiated research trial will have a Champion designated by the President with approval of the Board of Directors. The study Champion will be an Active DUCCS member. The DUCCS champion's additional responsibilities include:

- 1. Review list of potential sites and identify sites to be invited to participate
- Serving on the study's Steering Committee and/or Publication Committee if approved by the sponsor
- 3. Frequent interactions with the DUCCS Administrative Director and with the PIs from each site in an effort to facilitate and maximize each sites study performance (minimum of monthly conference calls with site PI's)
- Provide an update of the study to the Board of Directors during the bi-monthly conference call

DUCCS RESEARCH GUIDELINES

A study can be offered to DUCCS members if there is a signed contract for participation of DUCCS in the study either as the sole investigator, as a consortium, or if the study protocol was approved by the DUCCS Board of Directors.

Final study approval requires:

- 1. Review of the final draft of the protocol.
- 2. Review of the scientific merits of the study as described by the study principal investigator.
- 3. Review of the funding of the research sites and DUCCS office.
- Consideration of possible conflicts of this study with previously approved or potential future DUCCS protocols.

CONFLICTS OF INTEREST

All investigators are required to submit a Conflict of Interest Statement prior to the initiation of a clinical trial. These statements will be updated annually or sooner as appropriate.

DUCCS FINANCING

DUCCS operational funds will come from:

- 1. Annual active membership fees.
- 2. Industry grants.
- 3. Retainer fees by industry.
- 4. Funds from individual sites for site improvement.
- 5. Gifts and donations
- 6. Galen Wagner Endowment Fund
- 7. Duke University
- 8. Other sources as developed

Expenses

- 1. The DUCCS will pay the salary and benefits of a full-time Administrative Director.
- 2. The DUCCS will maintain an operational office located at Duke University.
- The DUCCS President and Vice President will be reimbursed for all reasonable expenses incurred to travel to Durham, NC to attend DUCCS organizational meetings as well as to the national meetings.

ENDOWMENTS

Endowments that are generated in the name of DUCCS, for the purpose of DUCCS, or in the name of a member of DUCCS who requests that the endowment is dedicated to DUCCS will be developed. The DUCCS Board of Directors will serve as the DUCCS Endowment Board with stewardship for the funds according to the rules for endowments established by Duke University.

The DUCCS Administrative Director will be responsible for the tracking and reporting the status of the Endowment funds to the DUCCS Board.

DUCCS PARTNERSHIPS AND AFFILIATIONS

The DUCCS officers and organization will seek to form partnerships and affiliations which foster its mission and continued viability. Such agreements shall not infringe on the autonomy

of the DUCCS organization. All such agreements will require ¾ of approval by the DUCCS Board.

DUCCS INDEMNIFICATION

DUCCS is solely responsible for the content of its activities and publications. Individual DUCCS members, Officers, members of the Board of Directors and Duke University will not be held liable for any expenses, fees, or penalties incurred in the conduct of DUCCS activities or clinical trials or symposia.

DUCCS SUB-Groups

The DUCCS Board of Directors can recommend and approve the development of a sub-groups within the DUCCS organization. The idea of the sub-groups is to develop a network of DUCCS members with a specific field of interest. The activities of the sub-group will be reported to the Administrative Director, who will provide a report to the DUCCS Board during the bi-monthly Board Call. The sub-groups will be led by a chair, who has the authority to approach industry and research organizations for potential collaboration on clinical trials and funding. However, before any contracts are signed, the approval must be obtained from the DUCCS Executive Committee. All monies obtained by the sub-groups will fall under the purview of the chair of the sub-groups with a 10% tax given to the DUCCS organization. The guidelines for the sub-groups will adhere to the DUCCS Constitution.

DUCCS GLOBAL/INTERNATIONALSITES

The DUCCS organization encourages the development of international sites under the following conditions:

- 1. The governance of an international site will not conflict with any of the goals, missions or constitution of DUCCS or Duke University.
- 2. The DUCCS organization, its members and Duke University are not liable for the financial or professional liabilities of any site.
- 3. All international sites require the majority approval of the DUCCS Board. A ¾ board vote is required to discontinue an international site without cause.

DUCCS CONSTITUTION

The DUCCS Constitution can be amended only by a majority vote of the Active members. The board will have three weeks to review proposed amendments. A ¾ majority vote of the Board is required prior to the presentation of the constitutional amendment to the full Active DUCCS membership.

APPENDIX 1: BENEFITS OF DUCCS MEMBERSHIP

Active Members:

- 1. Are eligible for election to the Board of Directors.
- 2. Can make nominations and can vote for officers to the Board of Directors.
- 3. Can sponsor non-Duke colleagues for DUCCS Active Membership.
- 4. Can propose new DUCCS sub-groups.
- 5. Can serve on the DUCCS Steering Committees.
- 6. Can propose new DUCCS studies.
- 7. Can participate in the Visiting Professor program.
- 8. Can participate as site-PI for DUCCS studies.
- 9. Can participate as members of DUCCS sub-groups.
- 10. Can participate in closed DUCCS meetings.
- 11. Access to collaboration with other research sites, professionals and organizations.
- 12. Engagement in taking new research ideas quickly from concept to implementation (Investigator initiated studies).
- 13. Receipt of the DUCCS newsletter.
- 14. Can participate in electronic mail, networks, etc, regarding research areas of interest.
- 15. Access for your study coordinator to the DUCCSinator network.
- 16. Access to coordinator training.
- 17. Facilitated access to CME.
- 18. Placement/employment opportunities.