American Burn Association Multi-Center Trials Group Bylaws

I. Name and Structure
   A. The organization shall be known as the American Burn Association — Multi-center Trials Group (ABA-MCTG)
   B. The ABA-MCTG is an affiliate organization of the American Burn Association. The ABA-MCTG shall have the mission, structure, membership, and other organizational and operational components as set forth in these bylaws, as approved by the ABA-MCTG Steering Committee and the ABA Board of Trustees, and as may be amended from time to time and approved by same.
   C. The ABA-MCTG will operate under the oversight of the ABA Board of Trustees and provide reports, at the Interim and Annual ABA Board of Trustees Meetings, describing the peer review process and other matters related to protocol design, research-agenda setting, quality assurance, patient safety, grant applications and awards, multi-center trials in process or planned, and such other matters as the ABA Board of Trustees may request.

II. Purpose
   A. Mission Statement
      The American Burn Association Multicenter Trials Group is dedicated to optimizing the outcomes of care for burn injuries through multi-center evidence-based research. The ABA-MCTG will provide the leadership, education and infrastructure needed to facilitate research collaboration and information exchange among researchers, burn care providers, and the communities they serve.
   B. Research Agenda
      The research agenda of ABA-MCTG will be focused on achieving the goals of the mission statement. In general, however, the research agenda will follow that of pre-existing consensus-derived research agendas of the American Burn Association (ABA).

III. Committee Structure
   A. ABA-MCTG Steering Committee and Other Committees
      1. ABA-MCTG Steering Committee
      2. Protocol design and review Committee
      3. Feasibility and budget Committee(accounting, clinical coordination, statistical)
      4. Data management and analysis Committee
      5. Quality assurance, safety and regulatory Committee
      6. Grant/Publication Committee
      7. Data Safety Monitoring Board (DSMB)
         A DSMB will be formed as needed for individual studies. It will operate independently of, but report to, the Steering Committee.
      8. Data Management and Coordinating Center (DMCC)
      9. Working Groups
      10. Individual Study Lead Centers (ISLC)
      11. Burn Center Affiliates (BCA)

IV. ABA-MCTG Membership
   A. Network Membership
      1. Active members are defined as individuals who are participating within the
structure of ABA-MCTG as set out under section III.

2. In addition, members of the Board of Trustees, as well as the Executive Director and Associate Executive Director of the American Burn Association will be considered Active members.

B. Steering Committee and Other Committee Membership

Only active members of ABA-MCTG may serve as members of the ABAMCTG Steering Committee and chair other Committees.

1. Steering Committee

The voting members of the Steering Committee will consist of 7 members. No more than five members can be physicians.

2. Other Committees

The chair of each Committee will be selected by the Steering Committee. Each Committee chair will appoint additional members essential for functioning of the committee subject to approval of the Steering Committee. All Committee members have voting privileges within the Committee.

V. Officers of the ABA-MCTG

A. Steering Committee

1. Steering Committee Officers

Officers of ABA-MCTG Steering Committee will include the Chair, Vice-Chair, Treasurer, and Secretary. All officers will be voted into office by the steering committee.

2. Duties of the ABA-MCTG Steering Committee officers:

a. Duties of the ABA-MCTG Steering Committee Chair are primarily those of overseeing the operation of ABA-MCTG, including coordinating and running the Steering Committee meetings, and, maintaining ongoing communications with all other entities, including the ABA Board of Trustees.

b. Duties of the Vice-Chair include assisting the Chair with ABA-MCTG responsibilities, as deemed necessary. The Vice-Chair may officiate at meetings in the temporary absence of the Chair. If the Chair becomes unable to perform his/her duties as determined by a majority of Steering Committee members, the Vice-Chair will assume the Chair’s responsibilities and will initiate a vote by the Steering Committee to select a new Chair.

c. The ABA-MCTG Secretary will be responsible to ensure that careful and authentic records of Steering Committee proceedings are kept. These duties will include carefully reviewing Steering Committee minutes and summaries for their accuracy and integrity. The Secretary will also maintain an updated list of all committee officers and members and ensure that a copy of the ABA-MCTG bylaws is available at all Steering Committee meetings. The Secretary will be responsible for posting and/or publishing Steering Committee minutes and communications to the American Burn Association and the ABA-MCTG website, as directed by the committee.

d. The ABA-MCTG Treasurer will be responsible for managing any and all financial dealings of the ABA-MCTG in cooperation with the ABA Board of Trustees.

B. Officers of Other Committees

1. Committees will be led by a Chairperson.

The duties of these Chairs will be to oversee the operation of their
Committees as directed by the ABA-MCTG Steering Committee. This includes appointment of Committee members. These Chairs will report to the ABA-MCTG Steering Committee.

C. Terms of Office, Qualifications, and Elections
   1. Terms of Office
      a. Steering Committee officers will be elected by the voting members of ABA-MCTG and their initial terms shall be as agreed to by the officers but not to exceed five years. Subsequent terms of officers will be for five-year terms and be staggered so that no more than two officers are elected each year, ensuring continuity of leadership.
      b. All other committee members serve 5-year terms.
   2. Qualifications
      a. The Steering Committee Chair must be a member of the ABA, and have previously served on the Steering Committee. He/she must have a MD or PhD and be actively participating in clinical burn research.
      b. The Committee Chairs of other Committees must be members of the ABA-MCTG and if they are not a member of the Steering Committee, they and will attend Steering Committee meetings by invitation only.
   3. Elections
      Steering committee members will be elected by ballot vote on the ABA-MCTG website or at the ABA Annual Meeting. The Steering Committee will nominate at least one person for each available position on the steering committee and nominations will be received from the ABA-MCTG membership. Winning candidates will be those who receive the most votes.
   4. Chairs of Other Committees
      Chairs of other Committees are appointed by the Steering Committee Chair and must be ratified by at least four out of seven members of the Steering Committee.
   5. ABA-MCTG Steering Committee members, officers, and other Committee Chairs can be removed from office by majority vote of the Steering Committee.

VI. Meetings
   A. Frequency of meetings
      1. ABA-MCTG Membership
         The ABA-MCTG group will meet at least annually at the American Burn Association Annual Meeting.
      2. Steering Committee
         Steering Committee meetings will be held at least annually and additionally as deemed necessary. It is the duty of the Steering Committee Chair to call meetings but a meeting can be called by a majority vote of Steering Committee members. There will also be provisions for electronic meetings, as necessary.
      3. Other Committees
         Committee meetings will meet at the direction of the Committee Chair. Reports from the Committees will be made to the Steering Committee at least annually.
   B. Alternates
      Alternates for Steering Committee and other Committee members who cannot attend a specified Steering Committee or other Committee meeting must be designated by the committee member and approved by either the Chair or Vice-
Chair of the Steering Committee.

C. Voting

1. Membership voting
   Decisions are made by majority vote of those votes cast, one vote per member, with two-thirds vote required under special conditions as determined by the ABA-MCTG-Steering Committee (per ABA-MCTG bylaw guidance and Robert’s Rules of Order).

2. Committee voting
   Decisions are made by majority vote of those votes cast, one vote per member or alternate, with two-thirds vote required under special conditions as determined by the ABA-MCTG-Steering Committee (per ABAMCTG bylaw guidance and Robert’s Rules of Order).

D. Quorum

1. Steering Committee
   Steering Committee quorum consists of at least five members or alternates.

2. Other Committees
   Committee quorum is defined as a majority of those members who attend Committee meetings, either in person or electronically. The Committee Chair or alternate must be present.

E. Robert’s Rules of Order, Meeting Confidentiality, and Open Meetings

   1. Robert’s Rules of Order will be used to conduct all ABA-MCTG meetings.
   2. ABA-MCTG Steering Committee and Other Committee meetings are open to all, unless the Committee decides by majority vote to keep a meeting closed.

VII. Committees

A. Standing Committees

   1. There are six Standing Committees.
      a. ABA-MCTG Steering Committee
      b. Protocol design and review Committee
      c. Feasibility and budget Committee (accounting, clinical coordination, statistical)
      d. Data management and analysis Committee
      e. Quality assurance, safety and regulatory Committee
      f. Grant/Publication Committee

B. Duties

   The descriptions and duties of the Standing Committees are described in the Policies and Procedures manual.

C. Ad hoc committees

   The Standing Committees may establish ad hoc committees as necessary to carry out the work of the organization.

VIII. Policies and Procedures

A. The ABA-MCTG Policies and Procedures manual is a separate document from the ABA-MCTG Bylaws. The Policies and Procedures manual contains the descriptions and duties of the ABA-MCTG Standing Committees, as delineated by the Steering Committee and with its approval. The Policies and Procedures manual will be maintained on the ABA-MCTG website (abaresearch.org).

IX. Code of Ethics

All ABA-MCTG members will be held to the highest ethical principles and standards consistent with the Federal Regulation for Protection of Human Subjects (HRSA
Circular No. 96.05, Code of Federal Regulations Title 45 Part 46 [45 CFR Part 46], and the Belmont Report). This includes, but is not limited to, compliance with any and all federal, state or institutional regulations regarding the performance of research.

X. Conflicts of Interest
A. All ABA-MCTG members are subject to the conflicts of interest policies of their respective educational institutions' policies and applicable federal laws and regulations (per 42 CFR Ch. 1, Subpart F, 50.6), state laws and regulations, and local institutional policies. Potential conflicts of interest are situations which might not allow for impartial or objective determinations. These situations include, but are not limited to, relationships with products, devices, government or companies such as pharmaceutical, formula, or equipment manufacturers. This would also include the receipt of research support or lecture honoraria from such companies or organizations.

B. In addition to the mandated requirements listed above ABA-MCTG members having any real, perceived or potential conflicts of interest in the development and testing of any drug, technique, methodology or technology are also required to disclose these conflicts to the ABA-MCTG Steering Committee at the time the conflict is recognized. These conflicts will be reviewed by the Steering Committee, which may deem it necessary to limit the role of the member in specific research endeavors in order to ensure scientific objectivity. Failure to disclose these conflicts of interest as required may result in the loss of the privilege to participate in ABA-MCTG and may be subject to disciplinary action by the ABA.

XI. Bylaw Amendments
A. Amendment proposal.
   Proposed bylaw amendments may be presented to the Steering Committee by any ABA-MCTG member.

B. Amendment ratification
   Amendment of these bylaws will consist of providing written notification of proposed amendments on the ABA-MCTG website and announced at least one year in advance at the ABA-MCTG meeting conducted at the ABA Annual Meeting. The amendment will be ratified by a majority vote of ABA-MCTG members conducted via the ABA-MCTG website.

XII. Construction and Severability
Applicable Illinois laws are hereby adopted as part of these bylaws. If any provision of these Bylaws is in conflict with any Federal or State of Illinois statute, the statute prevails. If parts of the Bylaws are judged illegal, the remainder survives.

Adopted by the ABA-MCTG Steering Committee __________________, 2007.

Adopted by the ABA Board of Trustees ________________________, 2007