

Constitution and Bylaws of the Australian Consortium of Centres for Clinical Cognitive Research (AC4R).

Terms and Privileges of Membership:

- Agrees to the principles and guidelines of these bylaws.
- Agrees to meet “Conditions of Participation;” i.e., active involvement in committee meetings, review of new projects or protocols, feasibility assessments and other related activities essential to the success of AC4R.
- Agrees to ensure data submitted to AC4R is complete and accurate and provided by pre-established deadlines. This includes a full commitment to ensuring, to the greatest extent possible, the integrity and accuracy of all data submitted.
- Membership achieved by meeting the “Conditions of Participation” as above, entitles members associated with AC4R to full participation in all activities to which the “Conditions of Participation” apply.
- AC4R data not previously published or presented publicly may not be used or presented in any way without the full agreement of all members associated with the AC4R.
- Publication and authorship of AC4R data may only be made with the consent of AC4R Executive.
- Any form of intellectual property (patents, trademarks, copyright or licenses, and resources resulting from such intellectual property) that is generated through the collective activities of AC4R will be shared equally by all the members of Committee which were actively involved in the process leading up to the creation of the intellectual property.
- All individual members pledge not to undertake legal action against one another or Committee in case of disputes related to AC4R. Grievances will be submitted to the AC4R Executive Committee for resolution.
- Failure to abide by all terms and conditions of these bylaws and/or “Conditions of Participation” for any future activities will result in termination of access to Committee data generated and loss of permission to utilise any such data.

ARTICLE I – NAME AND OBJECTIVES

This organization shall be known as the Australian Consortium of Centres for Clinical Cognitive Research (AC4R), representing a group of scientific and medical investigators who are committed to the cooperative planning, implementation, analysis and reporting of controlled clinical trials and of other research for Alzheimer's disease and cognitive related disorders. To this end, the AC4R aims to collectively attract more clinical trials into the Australian region.

ARTICLE II – ORGANIZATION

The AC4R, founded in 1999, is organised as a non-for-profit committee of members (scientific and medical investigators) who are interested in and are involved in clinical trials. The views of the AC4R do not necessarily represent the views of the institutions with which the investigators are affiliated.

ARTICLE III – INCOME AND EXPENSES

Any income or property of the AC4R shall be applied solely towards the promotion of the objectives of the AC4R as set forth in Article I, and no portion shall be paid or transferred to any officer, member or employee of the AC4R, except for pre-approved salary, reasonable reimbursement for work performed, and reasonable and proper remuneration including repayment of out-of-pocket expenses in return for any service actually rendered to the AC4R. True accounting shall be kept of the sums of money received and expended by the AC4R.

ARTICLE IV – AC4R HEADQUARTERS

The office of the AC4R will be located

ARTICLE V – MEMBERSHIP

Members of the AC4R need to be financial member

ARTICLE VI – OFFICERS

The AC4R shall be governed by a President, Vice President, Executive Director, Treasurer and any other officers as the members shall duly elect.

The officers will hold their offices for a 2 year term or until their successors have been duly elected.

ARTICLE VII – EXECUTIVE COMMITTEE

The AC4R member may elect an Executive Committee (to have from 4 to 9 members each having a 2 year term).

The Executive Committee shall be responsible for:

1. Developing and supporting the scientific projects of the AC4R including but not limited to the review of research protocols, and selection of steering committees for these research projects,
2. Reviewing and approving the appointments of the chair and members of any standing AC4R committees,
3. Formulating and maintaining standards for the AC4R regarding the conduct of trials, publication policies, and conflict-of-interest guidelines,
4. Overseeing the program and activities of the AC4R including any meetings, symposia and other administrative and scientific activities,
5. Formulating and maintaining current and accurate listings of members and of other qualified investigators who request participation in AC4R trials and programs,
6. Formulating and maintaining current and accurate listings of a members' capabilities database of AC4R member sites,

ARTICLE VIII – NOMINATIONS AND ELECTIONS

In the event of the death, resignation or vacancy of an officer or member of the Executive Committee, the following provisions shall apply. In the event of the death, resignation or vacancy of the President, the Vice President shall succeed the President for the balance of his or her elected term. In the event of the death, resignation or vacancy of the Vice President (including his/her succession to chair as described above), the President shall appoint a replacement from the current members of the Executive Committee. Such replacement shall be approved by majority vote of members of the Executive Committee and shall be voted upon by the voting membership of the AC4R at the next regularly scheduled election. In the event of the death, resignation or vacancy of an elected Executive Committee member, the position shall remain vacant until the next regularly scheduled election, at which time the voting membership of the AC4R shall elect a replacement to complete the remaining term of the departing member.

ARTICLE IX – AC4R TRIALS

Any member of the AC4R (or outside study sponsors), may make application to the Executive Committee for authorisation of an AC4R trial by submitting a sufficiently detailed summary or outline of the proposed protocol. In its decision as to whether or not to authorise a trial (or be involved with the trial), the Executive Committee shall comment on the aims, objectives, scientific and clinical adequacy of the protocol, qualifications and capabilities of the investigators, mechanism for funding and sponsorship for the proposed trial.

Each member will be informed of each trial presented to the AC4R. If interested in conducting the trial, they must present reasonable evidence that they can 1) provide adequate staff (investigator and coordinator), 2) Recruit sufficient subjects, and 3) Provide adequate space and equipment, for the trial being offered. If, in the opinion of the executive committee, these conditions have been met, the study may be offered to that institution depending on the size of the study. This process will be known as study feasibility.

The executive committee will be responsible for confirmation of site investigators for that study.

ARTICLE X – AC4R PUBLICATION POLICIES

1. All articles utilizing data on patients recruited as part of a study must acknowledge support from the study sponsor(s), unless advised by the sponsor that an acknowledgement is not necessary.

2. Peer-reviewed articles on the major objectives and general demographic descriptions of the study populations should have as authors either the Australian Consortium of Centres for Clinical Cognitive Research with membership listed in a footnote, or some or all of the members of the AC4R in the following order: the primary author, the primary biostatistician, AC4R investigators in order of the number of their patients enrolled in the study, AC4R site coordinators in order of their investigators, AC4R members without responsibility for subjects, and the Principal Investigator and Co-Principal Investigator if not the primary authors. Authorship on reports of ancillary studies should be decided by those who proposed the ancillary study to the steering committee.

ARTICLE XI – CONFLICT-OF-INTEREST GUIDELINES

Individual members of the AC4R should maintain the highest personal and professional standards in conducting clinical trials and research. Real and perceived conflict-of-interest must be avoided.

To these ends, we agree that:

1. AC4R individual members shall not in any way or manner personally benefit financially as a result of their participation in and knowledge of AC4R studies. In particular, AC4R individual members agree not to own or trade in the equity of a company whose drugs or products are being investigated by the AC4R (“involved company”). AC4R individual members further agree not to inform or influence relatives, friends or others in financial transactions regarding the “involved company”. AC4R individual members agree not to accept compensation arrangements in which the value of the compensation could be affected by the

outcome of the AC4R studies in which they are participating. In addition, individual members participating in an AC4R clinical trial agree not to hold a financial interest in the study drug or related drugs or products including, but not limited to, a patent, trademark, copyright or licensing arrangement.

2. Certain activities with “involved companies” are permitted, however payments received by the AC4R individual members must be disclosed to the Executive Committee via annual Conflict of Interest reports. These include serving as an educator in CME accredited programs sponsored by an “involved company” or participating in consulting or research activities supported by the “involved company” which are unrelated to the drug or product under evaluation.

ARTICLE XIII– DUES, FEES AND SURCHARGES

The Executive Committee may propose annual dues for AC4R members and fees (or surcharges for participation in AC4R trials) in order to support AC4R activities, including but not limited to the planning and implementation of AC4R trials, scientific and educational symposia, and its annual meeting. Proposals of the Executive Committee for dues, fees or surcharges will require approval by a majority of votes received from AC4R members who respond.

Money received by AC4R will be placed in a communal account set up by AC4R. This money may be distributed to individual members and consultants only in compensation for work done by those individuals on behalf of the consortium.

Debts incurred by AC4R are not to be considered debts of individual members of the committee or institutions associated with the consortium, except where indicated by contractual arrangement.

ARTICLE XIV – AMENDMENTS

Amendments to the Constitution and Bylaws may be proposed by any individual member, must be made in writing, must be signed by 2 other individual members, and must be submitted to the AC4R President at least 2 months prior to a meeting of the AC4R Executive Committee, at which time the proposed amendment will be considered and voted upon. If the proposed amendment is approved by a majority of the Executive Committee, it will be circulated via ballot to at least 1 member of each institution who will provide a consensus vote for that site. Affirmation by at least two-thirds of votes received by the Executive Director, within 1 month after the proposed amendment was circulated, shall be required for the amendment to be adopted.

At the request of the proposer, amendments not approved by the Executive Committees of the AC4R may be placed on the agenda at least two months prior to an annual AC4R meeting where the proposal may be enacted by an affirmative vote by at least three-quarters of votes cast by institutions at the meeting.

ARTICLE XV– DISSOLUTION OF THE AC4R

The dissolution of the AC4R shall be decided by an affirmative vote by written ballot of three-fourths of votes of members of the AC4R who respond.