

# Cardiac Safety Research Consortium

## CSRC

### Membership Committee Charter

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APPENDIX A – CSRC Membership Application

## **1. Purpose: The CSRC Membership Charter and CSRC Membership Committee Composition, Responsibilities, and Eligibility/Expectations for Participation**

The purpose of the CSRC Membership Charter is to describe and define the process by which individuals, companies, regulatory agencies and organizations become members and the aspects of their membership within the CSRC. Refer to the subtopics of the charter for more details:

- Membership Application Process
- Composition of Membership
- Requirements and Responsibilities for Membership
- Levels of the Membership
- Membership Dues
- Benefits of the Membership
- Duration of Membership
- Transition of Leadership
- Termination of Membership
- Nomination Process for Committee Participation and Leadership Transition

The purpose of the CSRC Membership Committee is included in the CSRC Membership Charter to briefly describe and define the responsibilities as it relates to the membership. More details of this committee are provided in the CSRC Governance Charter

### **Composition of the CSRC Membership Committee**

- Chair: Must be a full member of CSRC with at least 2 years prior membership.
- Co-chair: May be Advisory or Associate Member in selected cases.
- The Chair and Co-chair should have been part of the committee for at least one year. It is expected that the Co-Chairpersons are elected in different years and serve in this role for 2 years with one potential re-election. Longer tenure represents an exception and will require consensus.
- Membership to include at least one academic, one member from industry, and one member from regulatory.

As with all CSRC committees, all final decisions from the CSRC Membership Committee require approval by the CSRC Executive Committee

### **Responsibilities of the CSRC Membership Committee**

- Develop and maintain CSRC informational materials for potential new members
- Solicit, provide support and outreach for potential members

- Evaluate applications for CSRC membership, and present proposals to the EC
- Determine level of membership (Sustaining/Principal/Associate)
- Provide information on and facilitate new member opportunities within the CSRC
- Liaise with other CSRC Committees as needed to coordinate related efforts
- Periodic review of membership composition and participation

### **Eligibility & Expectations for Participation on the CSRC Membership Committee**

- Regular (>50%) participation in conference calls.
- If Membership Committee (MC) member cannot fulfill these expectations, then the member will be asked to step down by the chair(s).

## **2. CSRC Membership Application Process**

The CSRC Membership Committee develops and maintains CSRC informational materials for potential, new and current members. They also solicit, provide support and outreach for potential members to ensure diversity within the types of members (i.e. academic, start-up to large company, individual, regulatory, etc.).

All potential members will complete a membership application (Appendix A) that the Membership Committee will use for evaluation and determination of eligibility and membership level. Their membership level will be based on whether the potential member's application is from an individual, a regulatory agency, a society/organization or a company whose category is either "not-for-profit" or "for-profit". For companies, it will also be based on their proposed monetary commitment relative to yearly gross sales or monetary market capitalization for 1 or multiple years (e.g.3 years).

The potential members' application will include information on their interest and areas they would be collaborating within CSRC (e.g. proposed new project, their specific expertise or interest relative to an existing specific CSRC project/program. Based on this information, the Membership Committee will facilitate the new members opportunities within the CSRC.

Diversity of its membership is important to CSRC; hence, the Membership Committee also works to ensure the potential members and recommendations of current members to the various committees and projects are mutually aligned and will continue to build a collaborative environment to advance cardiac safety scientific knowledge and other public health priorities.

### 3. Composition of CSRC Membership

The membership of the CSRC is composed of representatives from the major stakeholders including, but not limited to, academia, the pharmaceutical industry, biological industry, device industry, professional societies, trade organizations, contract research organizations, core laboratory organizations, patient advocate groups and interested regulatory agencies. These major stakeholders are not limited to United States representation but may include participation from international representations composed of similar major stakeholders previously noted. All the above is working together toward the common goal of a better understanding of cardiovascular clinical safety in development.

The CSRC seeks active participation of all its members. Each member is expected to make meaningful contributions and actively participate in the work of the consortium. They are encouraged to attend at least one face-to-face meeting each year. All members are also expected to make contributions-in-kind, including data, technology, manpower, or other needed resources to achieve the mission and support activities of CSRC.

The CSRC members fall into three categories:

- **Not-for-profit organizations** (e.g. academic institution, societies/organizations, regulatory agencies, etc.)
- **For-profit companies/organizations** (e.g. biopharmaceutical corporations, contract research organizations, core laboratories, technology companies, etc.)
- **Individuals** (e.g. cardiac safety consultants, advisors, academic scientist/educators, individuals from regulatory agencies, etc.)

The CSRC recognizes that there are individuals who may work part-time for a larger company and work part-time as a consultant. In order to avoid ambiguity, the CSRC will define a potential individual member as:

- a person who has a full-time appointment at an academic institution;
- works for a regulatory agency, or
- provide consultative services on a fee-for-service basis as their sole source of income, and does not receive a significant source of income from another company such as biopharma, CRO, laboratory, etc.

Part-time employees of a company are not eligible to become members of the CSRC as an individual but can become involved in the activities of the CSRC if their employer becomes a member of the CSRC or if their expertise is needed for a CSRC project..

#### 4. Requirements for CSRC Membership

In order to be granted membership to the CSRC, applicants must agree and meet all membership requirements. The means by which these requirements are provided may differ based on the category of the member (not-for-profit, for-profit, individual, etc.) and the level of membership (see below). All members are expected to make meaningful contributions to and actively participate in the work of the consortium. This participation may include, but not limited to, committee meetings (face-to-face as well as by teleconference); attendance at various CSRC sponsored meetings; creating, writing &/or review of CSRC educational or supportive documents; and/or collaborations on CSRC or CSRC endorsed research projects, programs and teams. The frequency of these activities will be determined by the project or program committee/team.

The contribution requirements of the CSRC membership are based on three criteria:

- **Financial contribution** (e.g. membership fee, support establish data warehouse, support consortium program/project, etc.)
- **Contribution of in-kind** attributes to be shared within the consortium (e.g. technology, data, expertise, etc.)
- **Contribution of manpower and expertise** to support the consortium's programs and collaboration.

The CSRC recognizes the importance of its diverse membership. The various ways its members support and contribute to the CSRC mission has enhanced the CSRC's ability to address and achieve its mission.

#### 5. Levels of CSRC Membership

The final decision on level of membership will be based on the type of contribution-in-kind set forth in the application, the level of anticipated involvement, and the justification for the proposed financial contribution.

From 2006 to 2012, the CSRC had four levels of membership (i.e. Founding, Sustaining, Principal and Associate). The original Founding CSRC Members included 5 companies (i.e. Cardionet, Daiichi, GlaxoSmithKline, Pfizer and Roche) along with several organizations and individuals who were nominated by the CSRC as meeting the criteria for full membership. This level of membership was retired in January 2012.

Currently, there are three levels of CSRC membership (i.e. Sustaining, Principal and Associate). These levels of membership were designed to distinguish the different levels of participation based on level of commitment and contribution by

the member. These three levels of membership applied to all three categories of not-for-profit organizations, for-profit organizations and individuals.

### **Sustaining Members**

The requirements for the Sustaining Members are based on criteria (contribution of data, contribution of manpower, expertise and financial contribution). The relative financial contributions are based on the amount of yearly gross sales or monetary market capitalization for start-up, small, medium and large companies. Sustaining Members are those members who have committed to and will continue to make, a multi-year financial commitment to the CSRC.

Members at this level who demonstrate specific interest, talents and expertise for a given leadership or governance committee opportunity are determined by the Executive Committee. The transition of CSRC leadership roles are described in the CSRC governance charter.

### **Principal Members**

All the requirements and leadership eligibilities for the Principal Member are the same criteria as the Sustaining Member. However, the Principal Member agrees to a financial commitment to CSRC for 1 year. If a Principal Member is of good standing, the member may renew the membership.

### **Associate Members**

Associate Members are defined as individuals, companies, and organizations who would like to be involved in CSRC activities but at a lesser level of financial and time commitment. Such commitments may include various combined contributions of financial, data, manpower and/or expertise as proposed by, and based on the resources of, the membership candidate, with review for approval by both the Membership Committee.

In addition, the members at this level are not eligible for nominations for a position on a CSRC governance committee leadership. However, this level of membership may lead a research team, but only in association with a sustaining/principal member.

If an Associate Member is of good standing, the member may renew the membership.

**Level of Membership by Company Market Capital & Commitment:**

	<b>Sustaining</b>	<b>Principal*</b>	<b>Associate*</b>
<b>Large Companies -</b> (market capitalization of > \$3 billion or yearly Gross Sales > \$1 billion)	\$25,000 per year with a 3-year commitment	\$27,000 per year	\$8,000 per year
<b>Medium Companies -</b> (market capitalization of \$250 million - \$3 billion or yearly gross sales \$50 million - \$1 billion)	\$10,000 per year with a 3-year commitment	\$12,000 per year	\$4,000 per year
<b>Small Companies -</b> (market capitalization of < \$250 million or yearly revenue < \$50 million)	\$4,000 per year with a 3-year commitment	\$6,000 per year	\$2,000 per year
<b>Start-Up Companies</b> (market capitalization - \$0 AND yearly gross sales - \$0)			\$1,000

\*Requires renewal each year

**5. CSRC Membership Dues**

Annual dues will be required for all members who meet the criteria of start-up, small, medium or large companies. (Refer to Level of Membership chart in section 4).

Potential company members that anticipate difficulty in making the suggested financial contributions are encouraged to contact the CSRC membership committee at [cardiacsafety@mc.duke.edu](mailto:cardiacsafety@mc.duke.edu) for a consultation. In rare circumstances, the CSRC will consider proposed alternatives from groups wishing to join the consortium although consideration will only be given to companies and organizations that are willing to provide a significant amount of data to the consortium or a significant amount of manpower relevant to the work of the CSRC.

**6. Benefits of CSRC Membership**

The primary benefits for being a CSRC member are:

- To be in a collaborative diverse network of academia, industry, professional societies, patient advocacy groups, and global regulatory agencies for mutual educational opportunities that allow the optimal use of time, talent and dollars.
- To use a supportive environment to have a “voice” that enhances public health & patient safety through better and advance scientific and clinical

understanding in the development of new medicines, devices and tools for assessment.

- To share & explore ideas/data in an intellectual protected environment.
- To openly discuss “hot topics” focused on practical cardiac safety issues to assist healthcare professionals in the clinical management of patients.
- To rapidly disseminated “lessons learned” through peer reviewed publications because of a collaborative agreement with the American Heart Journal.

All the above and more embody the mission and core key objectives of CSRC.

The level of membership determines the members’ eligibility for leadership positions on CSRC committees and research teams, reduced registration fees for CSRC meetings, and eligibility for participation in CSRC leadership meetings\*\*\*.

**Benefit Chart for CSRC Members based on Level of Membership:**

	<b>Sustaining</b>	<b>Principal</b>	<b>Associate</b>
Eligible for seat on Executive Committee and/or a Leadership Position of one of the CSRC Governing Committees	X	X	
Eligible for Leadership of Research Team*	X*	X*	X**
Eligible for participation in a Research Team	X	X	X
Registration fees for CSRC Think Tank and General Meetings ***			
Waived Fees	1	0	0
50% Discounted Fees	3	1	0
20% Discounted Fees	2	2	1
Access to Early Registration for CSRC Think Tank and General Meetings	X	X	X

\* Sustaining or Principal membership is required to lead a research team

\*\*An associate member may lead a research team only in association with a sustaining/principal member

\*\*\* Numbers refer to number of participants eligible per meeting. [NOTE: The goals and structure of CSRC Leadership Meetings are meetings that include senior thought leaders from academia, industry, and regulatory agencies on a specific topic.]

**7. Duration of CSRC Membership**

CSRC membership requires annual renewal (based on meeting the requirements and expectations of membership as described above). All individuals and regulatory agencies will not be required to submit a renewal application but will be contacted annually to confirm continued participation in the CSRC.

As long as an organization or individual maintains an active status as a member of the CSRC, they may nominate persons to participate in the activities and the committees of the CSRC. Eligibility for participation in leadership positions is



based on the level of membership. However, it is important to recognize that persons participating in the CSRC as part of a company/organization lose their status within the CSRC if that person leaves the member company. When such a status change occurs, the person involved in the CSRC may apply to be granted Associate Member status for 1 year if other significant in-kind contributions continue, based on the assessment of the Membership Committee. After this 1-year grace period, that person must either re-apply to the CSRC as an individual (if they are no longer working for an organization), or their new organization must apply for membership in the CSRC in order for that person to continue their participation in the CSRC. The following examples are meant to illustrate a few examples of these potential situations.

- Dr. A has been a full time academic at a university and has been working with the CSRC for two years as a Sustaining Member and currently has a position on one of the CSRC Governance Committees (e.g., Executive Committee) and participates in a Research Team. Dr. A then leaves his post at the university and takes a job with NewDrugCo Inc. (which has previously not been involved with the CSRC). If NewDrugCo Inc. joins the CSRC as a Principal Member, then Dr. A can remain in his positions and involvement in the CSRC. In the event that NewDrugCo Inc. does not join the CSRC, Dr. A must step down from his position on the Committee immediately and can apply to the CSRC for a temporary status as an Associate Member which if granted allows him to continue participating on the Research Team.
- Dr. B is a full-time employee of BigDrugCo Inc. which is a Sustaining Member of the CSRC. Dr. B has been working with the CSRC for two years and currently has a position on one of the CSRC Governance Committees (e.g., Membership Committee). Dr. B then leaves BigDrugCo Inc, and takes a job with NewDrugCo Inc. (which has previously not been involved with the CSRC). If NewDrugCo Inc. joins the CSRC as a Principal Member, then Dr. B can remain in his positions and involvement in the CSRC. In the event that NewDrugCo Inc. does not join the CSRC, Dr. B must step down from his position on Membership Committee immediately and can apply to the CSRC for a temporary status as an Associate Member which if granted allows him to continue participating on the Research Team.
- Dr. C works for BigDrugCo Inc, a Sustaining Member of the CSRC, has been working with the CSRC for two years, and currently has a position on one of the CSRC Governance Committees (e.g. Scientific Oversight Committee), and he chairs a Research Team. BigDrugCo Inc does not renew its membership with CSRC. Dr. B must step down from his position on the Committee and must step down as chair of the Research Team immediately and can apply to the CSRC for a temporary status as

an Associate Member for one year which if granted allows him to continue participating on the Research Team (although not as chair).

## **8. Transition of CSRC Leadership**

Members who occupy seats on major CSRC committees, including the Executive; Scientific Oversight; Membership; and Scientific Program may retain their seats for the duration of the tenure specified for each committee, as long as the member's company continues to retain sustaining or principal membership. However, if a committee member's tenure ends, it is not automatically assumed that a member from this person's organization will replace the member stepping down.

As all Sustaining or Principle members are eligible for committee seats, the Membership Committee will work with the respective committee to identify an appropriate replacement for the person stepping down. The Membership Committee will make a recommendation of the appropriate replacement to the Executive Committee. The CSRC Governance Charter provides detailed guidance and oversight of the balance and transition of members.

## **9. Termination of CSRC Membership**

The Membership Committee will review on an annual basis, the contributions and determine continued eligibility of each member. If during participation, it is determined that the member is not fulfilling his/her obligations, the member may be asked to step down.

If while membership, it is determined that a CSRC member has engaged in activities that the CSRC Executive Committee determines is detrimental to the consortium, the member (and/or the organization) will be asked to step down from any leadership position that they may hold, including seats on major committees, or research teams. Based on the nature of the detrimental activity, the CSRC Executive Committee may also require the member and/or organization to leave CSRC.

## **10. Nominations for CSRC Committee Participation and Leadership**

It is expected that participation in all CSRC committees will rotate on a regular basis. Once a person is nominated to a position in a committee, the committee will need to communicate this decision to the Membership Committee to make sure that the person meets criteria for that leadership position and/or a member of good standing. The nomination of the member to the given position remains with the specific committee and the approval is with the CSRC Executive Committee. Further criteria are specified in the CSRC Governance Charter.

### **APPENDIX A – Membership Application**

Name of Applicant:

Organization:

Address:

E-mail:

Describe the category that best describes your organization or status as an individual:

- Not-for-profit organization
- For profit company/organization (pharmaceutical corporations, contract research organizations, core laboratories, and technology companies)
- Individual (cardiac safety consultants, advisors, academics, individuals from regulatory agencies)

Briefly describe your organization or your role as an individual interested in cardiac safety:

Briefly explain your interest in CSRC:

Briefly explain planned contribution to CSRC:

- Financial (indicate \$ amount of the contribution and justification for any variance with regard to the suggest contribution from Section 5)
- Data (Describe whether you have access to and permission to share data with the consortium)
- Expertise (Describe the expertise you plan to bring to the work of the consortium)
- Technology (Describe any technology you plan to bring to the work of the consortium)
- Other (Describe)

Please provide the names and CVs/Resumes of the individual who will be participating in the CSRC.