CSRC 'WHITE PAPER' PUBLICATION POLICY

1. Purpose

The Cardiac Safety Research Consortium (CSRC) is a public-private partnership aimed to support research into the evaluation of cardiac safety of medical products. One of its outputs is the publication of consensus white papers with participation of experts from industry, academia, and regulatory agencies. These position papers usually cover challenging areas of cardiovascular safety, describing what is known and unknown, and propose paths forward to address knowledge gaps. These white papers are not regulatory guidances, nor are they intended to serve as de facto guidance documents.

This document aims to ensure that the CSRC position papers fulfill key premises including

a) consistent approach with clear procedures and responsibilities
b) scientific quality
c) conflict of interest disclaimers
d) regulatory disclaimers

2. Scope

This policy document applies mainly to CSRC white papers and publications describing key outputs from CSRC-sponsored 'Think Tank' meetings. Other CSRC publications (e.g. proposals and/or results from research studies) can use this document as a guide but they don't necessarily need to follow the same procedures.

3. Starting a writing group & recruiting members

The first step will be to submit the completed "Project Submission Form" (see appendix) to the CSRC White Paper Writing Group (WPWG) leader. The proposal will be evaluated by the WPWG and then presented to the Scientific Oversight Committee (SOC) for endorsement and assignment of an SOC member who will be part of this initiative and serve as SOC 'champion' for this particular publication. Typically, but not always, the person submitting the proposal will be the project leader and senior author of the publication.

Efforts should be made to avoid repetition of the same experts as authors in the CSRC publications. In order to encourage participation in the mission of the CSRC, new members (e.g. scientists not previously involved in CSRC papers), a trainee, a fellow or similar junior level scientist, whenever possible, will be designated as the "primary writer" of the manuscript under the guidance of the project leader. Typically, although not always, it is anticipated that the "primary writer" will be first author and the project leader will be senior/last author on the publication. However, ultimate authorship designations should be based on the amount and significance of contributions.

In the case of CSRC "Think Tank" proceedings, the "primary writer/scribe" will be designated in advance of the meeting and will personally attend and maintain detailed minutes/record of the "Think Tank" (often with assistance of other participants and audio recording). It is anticipated that the "primary writer" will maintain his/her participation in the project until publication.

Any subject matter expert can be part of the group putting together the draft publication, with the following premises

- The project leader must be a full member of the CSRC
- Typically, full or associate CSRC members are part of the list of authors in the final publication. Based on their level of participation, individuals not affiliated with the CSRC can be co-authors or acknowledged in the paper.

- The project should include participants from all the key CSRC stakeholders (i.e. academia, industry and regulators); absence of any of these groups should be justified.
- Authorship should be determined by the level of significant contributions of the writing group participants.

4. Manuscript preparation, review and endorsement

The manuscript preparation process should include the following steps

- The core writing group will have periodic meetings and create a first draft version with the "primary writer" coordinating section contributions from the other members of the core writing group under the close guidance of the project leader.
- Review of the first draft by the WPWG, the SOC and key regulatory stakeholders
- The core writing group will discuss the feedback received and create a second draft version for CSRC evaluation
- Key contents of the white paper should be discussed in an open forum session (e.g. webinar or face to face meeting, or be part of the discussions within a CSRC sponsored "Think Tank") where members of the CSRC are invited to provide feedback.
- The core writing group will incorporate the feedback received, and distribute the final version for endorsement by the CSRC Executive Committee and members of the regulatory authorities.
- The endorsed paper is ready for submission after sign-off by each one of its authors (each coauthor should seek the appropriate approval procedures within his/her organization).
- Documentation of these steps and review process will be maintained in order to demonstrate adequate "peer" review for submission purposes to the American Heart Journal.

5. Guidance for manuscript preparation

For each publication to be developed, there will be one person from the working group assigned to lead the initiative (project leader). It is his or her responsibility to ensure that the procedures are followed from its initiation to final dissemination of the publication. Authorship should be agreed upon, in principle, before development of any publication in accordance with the authorship criteria set forth in the "Uniform Requirements for Manuscripts Submitted to Biomedical Journals," http://www.icmje.org/urm_main.html. Membership in the working group does not constitute authorship in itself.

Only white papers with significant contribution and review from all stakeholders within the CSRC can be attributed to the CSRC, and the publication should include acknowledgement of this CSRC initiative.

The CSRC white paper manuscripts should focus on the available scientific data for a particular matter, explore areas for further evaluation, and present potential approaches to better understand cardiovascular safety issues in drug development. It is very important that the manuscript is written in a way that it cannot be considered as a regulatory guidance document, and clearly indicates that it does not represent an official regulatory position, regardless of the slate of participants or authors.

Based on scientific data available, the position papers should seek consensus on the matters included; however, when a unified approach can not be reached the publication should acknowledge areas where there are still divergent positions. Transparency should guide the manuscript writing process, and any relevant and publicly available scientific data supporting the concepts can be included. In the case of potential conflicts it is critical to have full disclosure.

6. Submission for publication

All publications must be prepared in accordance with the "Uniform Requirements for Manuscripts Submitted to Biomedical Journals," including appropriate references, citations, and acknowledgements. It should not use confidential data inappropriately. Potential conflicts of interests by all authors have to be declared in a transparent manner and should err on the side of inclusiveness.

All CSRC white papers should include a disclaimer indicating that the opinions and conclusions expressed in the manuscript are solely the views of the authors and do not necessarily reflect those of the regulatory agencies or any particular Pharmaceutical Sponsor.

Currently the CSRC has an agreement for publication of these types of manuscripts in the American Heart Journal; editorial review and publication approval will be expedited for those papers that have included extensive discussion and review by key stakeholders within the CSRC.

Commented [A1]: You mentioned a new affiliation with DIA?

Among the coauthors, a corresponding author will be identified who is responsible for all communications (e.g., with journal and CSRC) regarding the manuscript upon release by the CSRC.

APPENDIX

The Cardiac Safety Research Consortium (CSRC)
Project Submission Form

(Completion of this form is the responsibility of the 'white paper' leader. Not every section of this form is applicable to white papers since it is also used for other project submissions.)

1. Title of project concept		
2. Submission date		
3. Submitter name, title, email address, and phone number		
4. Name and address of submitting organization		
5. Name(s) of other partner organization(s), if applicable	Name of Organization	Organizational Contact
6. What scientific gap/public health need is addressed by this project? *Your answer should be limited to 150 words*.		
7. What technologies are addressed by this project (ECG, imaging, molecular, genetic, etc.)?		
8. Has the proposed concept received any formal review? If so by whom? Is it currently being evaluated elsewhere?		
9. What is the estimated budget for the project? Please specify: • Which parts of the funding are being covered externally with firm commitments? • Are there known and potential funding partners? • What other resources will be needed and how will these be obtained? • What, if any, funds/resources are being requested from the consortium?		
10. What is the estimated starting date and duration of the project?		
11. In lay language, state the objective of the project and its relevance to patients. *Your answer*		

should be limited to 50 words.	
12. Briefly describe the proposed project, including any preliminary results and evidence concerning feasibility. Provide up to 5 key literature references. *Your answer should be limited to 500 words (one page) not including references*.	
13. If not included in the project description, what statistical methods will be used to evaluate the findings?	
14. Are sufficient technology and data available to carry out this project? Please explain. *Your answer should be limited to 150 words.*	
15. How would the project benefit from a partnership under the CSRC? *Your answer should be limited to 150 words.*	
16. How will this project promote the understanding of the underlying (patho)biology of disease or health, advance public health and further the mission of the CSRC? *Your answer should be limited to 150 words.*	
17. How would this project facilitate medical product development and/or regulatory approval? *Your answer should be limited to 150 words.*	
18. Is the project linked to a particular commercial product? *Your answer should be limited to 150 words.*	
19. What are the prospects for development and commercialization of technologies developed in this project? *Your answer should be limited to 150 words.*	
20. If a specific investigator or group is proposed to do the work, please provide CVs as separate attachments.	