

# SCB Working Group Policy

The Standards Coordinating Body (SCB) for Regenerative Medicine was founded in 2016 as a 501(c)(3) not-for-profit entity resident in the State of Maryland. SCB's involvement with standards development is increasing daily, both nationally and internationally. This standards development is often completed through the establishment of SCB working groups. SCB working groups are collaborative forums where subject matter experts and relevant stakeholders can discuss areas identified by the regenerative medicine community to be most relevant and impactful. Working groups are formed to address shared issues faced by the regenerative medicine community. The outputs of these working groups include, but are not limited to, feasibility studies, drafted standards, white papers, guidance documents or the coordination of round robin testing. SCB is unbiased in fulfilling its mission. There are multiple ways that corporations, organizations and individuals can be involved in working groups. SCB welcomes all regenerative medicine stakeholders, working group participation is entirely voluntary and all stakeholder inputs are equally considered.

**Scope:** All of SCB's activities involve facilitating interactions amongst for-profit entities and other relevant stakeholders within the regenerative medicine community with varying points of view and expertise. This document is meant to describe and define the expectations of working group members and the subsequent work products.

## Call Decorum

- Treat all members with respect
- Effort to give everyone a chance to voice their opinion
- No abusive language
- Working group members can join as individuals or representatives of their organization
- Following these policies is conditional for an individual's participation in a working group and other SCB activities

## Communication Materials and Intellectual Property

- It is recognized that some materials utilized in Working Groups are owned by organizations other than SCB
- SCB published content can only be distributed for authorized use or with written permission
- Any SCB materials used by groups shall be marked with SCB logo and accredited to SCB
- There can be no in-fact or implied exclusivity or non-SCB control in working group activities/products or any activity sponsored by SCB.
- All working group output will be created and distributed using SCB materials and include SCB logo and copyright mark unless otherwise limited by the SDO processes

## Working group operations and expectations

- Working group membership is voluntary
- Membership and decisions (discussions) are unbiased and open
- Decisions on standards projects are to be determined by the working group
- In the event that a working group is facing an impasse or unresolvable issue, either the Scientific Program Manager or SCB leadership will facilitate to reach a resolution

- SCB will be responsible for agenda items, leadership of meetings and the working groups
- The cadence of the working group calls is determined by the group and can be changed as standard development progresses
- All compiled comments and revisions are to be submitted directly to SCB
- SCB is responsible for archival and management of submitted materials

## SDOs, Publications, and Publishing

- SCB is not a Standards Development Organization (SDO) and therefore does not publish standards
- SCB presents and guides the standard or document to the appropriate SDO or journal
- The appropriate SDO or journal is determined by multiple factors, including the opinion of the group members, SDO/journal acceptance, timelines, audience factors, the level of technical detail, and other relevant factors
- Once a standard initiative is accepted by an SDO, SCB will follow the SDO processes and continue the facilitation and coordination of standard development
- If a standard initiative is accepted by an SDO, meeting cadence, document submission, timelines, comment periods, membership requirements, templates, and other working group considerations are determined by that SDO's processes.
- SCB recognizes processes of accreditation groups and government agencies that may take precedent
- SCB recognizes that professional organizations, pharmacopeias, and government agencies have organization- specific constraints for participation in groups like SCB. SCB will endeavor to facilitate full participation of groups in these efforts.

The SCB working group leader and all participating members are expected to adhere to these policies. To take part in SCB activities, compliance to this policy is required.