

SICKLE CELL DISEASE COALITION GUIDING PRINCIPLES FOR PARTICIPANTS

These Guiding Principles set forth the qualifications for initial participation and the conditions for continued participation in the Sickle Cell Disease Coalition. Entities wishing to participate in the Coalition initially must demonstrate that they meet the criteria applicable to the relevant participant category. Existing participants are expected to continue to meet the criteria applicable to their participant category and to conduct themselves in accordance with these Guiding Principles to continue their participation in the Coalition.

MISSION:

Sickle Cell Disease (“SCD”) is an inherited, lifelong disorder affecting nearly 100,000 Americans. Globally, it is estimated that one in every 250,000 infants are born annually with SCD. The majority of these births occur in low resource countries, especially in sub-Saharan Africa where the World Health Organization estimates 70 percent of the world’s population of children with SCD live. The Sickle Cell Disease Coalition (“SCDC” or “Coalition”) is an association of independent entities and organizations, spearheaded by the American Society of Hematology (“ASH”), involved in the effort to advance the treatment and cure of SCD.

The mission of the SCDC is to help amplify the voice of the SCD stakeholder community, promote awareness and improve outcomes for individuals with SCD. The Coalition will focus on promoting research, clinical care, education, training, and member advocacy* in an effort to deliver advances in treatment and care faster, more economically and more efficiently to SCD patients in the United States and throughout the world. The SCDC will serve as a platform to encourage stakeholders to work together to develop and implement important projects and activities that will ultimately help improve outcomes for individuals with SCD. ASH will support the initial administrative costs of the SCDC, and provide the initial administrative management of the Coalition.

COALITION PARTICIPATION:

The SCDC is comprised of public health, research and provider organizations; patient groups; faith-based organizations; federal agencies; * industry participants; foundations and other funding organizations with an interest in SCD. The Coalition currently is not offering participation by individuals, individual institutions (i.e. individual universities, hospitals, health care systems, etc.), and community, state, and regional-based organizations. The SCDC encourages national and global organizations to serve as the representative for these different types of constituencies. Individuals interested in staying abreast of Coalition news and activities are encouraged to register for SCDC updates by contacting the SCDC administrator.

New applications from entities desiring to participate in the SCDC will be reviewed by the SCDC Steering Committee to ensure that the applicant meets the criteria for the relevant participant

* Federal agency representatives will not participate in any SCDC discussions relating to advocacy.

category. The final decision about all participant applications and/or other participant issues will be made by the Steering Committee.

All SCDC participants are expected to comply at all times with any and all applicable laws and regulations governing their conduct in their respective jurisdictions, as well as these Guiding Principles. Particular considerations relevant to each of the SCDC participant categories are set forth below. SCDC participants should conduct themselves in a manner consistent with the primary focus of the Coalition, which is *the identification, promotion and application of the best available science to advance the treatment and cure of SCD*. All SCDC members are also expected to be active and engaged participants.

Public Health Organizations – Public health organizations with an interest in SCD and that are focused on the science of protecting and improving the health of people and their communities, by promoting healthy lifestyles, researching disease and injury prevention, and detecting, preventing and responding to infectious diseases.

Research and Provider Organizations – Organizations that represent a particular group of medical, or research professionals or entities with an interest in SCD. Research or provider organizations seeking to participate in the SCDC should provide information about the particular aspects of SCD on which their work is focused and should demonstrate the national or global reach of the organization.

Faith Based Organizations – A faith-based organization is an organization whose values are based on faith and/or beliefs, which has a mission based on social values of the particular faith, and which most often draws its activists from a particular faith group. Faith-based organizations can provide potential access for health education, promotion and interventions for individuals and families concerned with SCD.

Federal Agencies – Federal agencies and departments may participate in the Coalition, but may not participate in any advocacy or in discussions among Coalition participants relating to any advocacy efforts. If a federal agency is unable to officially join the Coalition because of restrictions at the agency, then it may be allowed to participate as an “ex-officio” member of the SCDC.

Industry Participants – Pharmaceutical, biotechnology and device companies that meet the following criteria are encouraged to participate in the SCDC, but they are not eligible to vote on SCDC matters or serve as members of the Coalition Steering Committee. To be eligible to be an industry participant member of the SCDC, a company must: (a) have a sickle cell disease-related therapy or device currently on the market or in an active phase 1, 2, or 3 trial; (b) demonstrate that it is incorporated and in good standing in its state of incorporation; and (c) maintain an active website. Industry participants should note that the SCDC is not a platform for promotion of commercial products and services.

Foundations -- Private foundation or grantmaking public charities with an interest in SCD, whose principal purpose is to provide grants to unrelated organizations, institutions, or individuals for scientific, educational, cultural, religious, or other charitable purposes. In the event that a

foundation is unable to officially join the Coalition because of internal rules, then it may be allowed to participate as an “ex-officio” member.

Patient Groups -- The SCDC has invited patient-focused organizations with a national and international reach to serve as the groups representing the SCD community. All US-based organizations need to have at least one national meeting and educational programing or classes.

Other National Groups or Organizations Focused on SCD – Other groups and organizations operating on a national or international basis and focused on research, clinical care, education, training, or advocacy relating to SCD may seek participation in the SCDC by demonstrating in writing to the Steering Committee how their participation will further the mission of the SCDC; such participation to be at the sole discretion of the Steering Committee.

INTERNAL CONDUCT BY COALITION PARTICIPANTS:

All SCDC participants are expected to deal with the Coalition and other Coalition participants fairly, ethically and in good faith. When providing information to other participants in the Coalition, participants are expected to be honest, accurate, objective and complete. Participants are also expected to keep confidential any information that may be provided to them on a confidential basis by the Coalition or another SCDC participant, unless authorized by the disclosing member or required by law to disclose the information.

Participants are encouraged to use the SCDC as a platform to inform other participating groups and organizations about their ongoing SCD-related work and invite other participating groups to help develop, implement and fund those and other SCD-related projects. However, Industry Participants may not use the Coalition, its facilities, or their Coalition membership to: (a) solicit investment or funding for general corporate purposes or any purpose unrelated to SCD; or (b) to sell, market or promote their commercial products or services or to discuss any aspect of such sale, marketing or promotion of their commercial products or services. An Industry Participant that attempts to use the SCDC for commercial sales, promotion or marketing purposes will receive a written warning, and if the conduct persists, the Industry Participant’s membership in the SCDC will be terminated.

Over time as the Coalition further defines its role, develops SCDC-generated projects and the Coalition’s portfolio grows, the Steering Committee will make a recommendation about how to address simultaneous priorities. The Steering Committee will also decide whether to develop additional small topic-based working groups within the SCDC.

EXTERNAL CONDUCT BY SCDC PARTICIPANTS:

Any and all external uses of the Coalition name, logo, materials, and activities are subject to the review and approval by the Steering Committee. No Coalition Participant may: (a) distribute non-public information about another Coalition member relating to that member’s SCDC-related activities without the permission of the other member; or (b) use its participation in the SCDC for grant, fundraising or other revenue-generating purposes without the prior express written

permission of the SCDC Steering Committee. No Coalition Participant or group of Participants may lobby Congress, state legislatures or other government officials, or engage in public advocacy in the Coalition's name.

The Coalition will publicly identify the names and logos of SCDC Participants on the SCDC website and in SCDC media materials unless the member requests that its name and/or logo not be used. The Coalition will not undertake, engage in, or continue any activity that might damage the reputation of the Coalition or its Participants, or result in the dissemination of biased or inaccurate information to the public concerning SCD or any SCD treatment.

The Coalition has a number of external communication vehicles, including the SCDC website, SCDC Update (e-newsletter), and SCDC Twitter handle, as a way to raise awareness about SCD, as well as provide updates about Coalition and member activities. Announcements will also be shared via SCDC meetings and calls, as well as through SCDC e-mail updates. All content will follow a set of guidelines and there is not a guarantee that all of the members' content will be included on the site. As noted above, commercial information will not be shared through SCDC communication outlets.

COMMERCIAL CONDUCT:

Participants are expected to conduct their business dealings with the Coalition, other Coalition Participants, and the public in general, lawfully and ethically. The Coalition will not endorse or promote any Industry Participant or its products. Likewise, participation in the SCDC should not be used to promote the commercial products or services of any particular participants or to discuss the terms or conditions of sale of such commercial products or services. The SCDC is not a platform for Industry Participants to promote their commercial interests.

FUNDING:

ASH will support the initial administrative costs of the SCDC and provide the initial administrative management of the Coalition.

The Coalition does not expect to provide funding for particular projects. Rather, the Coalition expects to provide a platform for SCDC Participants to inform other Participants of their SCDC-related projects and to partner with other Participants on projects that their organization is leading. These projects may have direct industry support, including support from Industry Participants. Despite participation by multiple SCDC members in these projects, they will not be considered Coalition-wide initiatives.

Projects initially developed and funded by SCDC Participants may be presented to the Steering Committee for approval as Coalition projects. The Steering Committee may recommend such projects for funding by Coalition Participants.

ADVOCACY:

Recognizing that each participating organization may have its own policies and priorities with respect to government advocacy: (a) no Coalition member may undertake or engage in advocacy before any federal, state or local government or government agency in the name of the Coalition; and (b) the Coalition will not undertake or engage in such advocacy before any such government or government agency.

Although the Coalition will not advance legislative or regulatory recommendations, it may serve as a forum for discussion of issues related to such purposes. However, each participating organization has the discretion to opt out of any such discussion. In addition, members of the Coalition, individually or collectively, may engage in such advocacy before federal, state or local governments or government agencies, provided that they do not do so in the name of the Coalition.

No Federal agency representatives will participate in Coalition discussions related to advocacy.

GOVERNANCE:

A representative group of seven Participant organizations will serve as the initial Coalition Steering Committee. ASH will serve as one of the groups represented on the Steering Committee and will provide the initial day-to-day administrative support for the SCDC. Six additional groups representing the different membership categories were invited to have a representative participate on the Steering Committee, with one position reserved for a global organization. The Steering Committee will: (1) help to identify additional organizations who should be part of the SCDC; (2) suggest strategy for the Coalition, which will be considered by SCDC Participants; (3) evaluate applications to participate in the SCDC and identify new Participants; and (4) rule on any disputes among SCDC Participants and enforce these Guiding Principles. The SCDC Steering Committee members will not have term limits. In the event that a Steering Committee member needs to step down or additional Steering Committee members are needed, the remaining Steering Committee members will nominate new Steering Committee members, and the voting members of the Coalition will then be asked to vote to fill the position.

VIOLATIONS OF GUIDING PRINCIPLES

A Participant ordinarily will be notified of the violation and asked to cease the violating conduct and/or to remedy it. Failure to cease the violating conduct or engaging in other conduct violating the Guiding Principles of the SCDC may subject the violating Participant to sanctions, up to and including revocation of its right to participate in the SCDC.