KCNQ2 Cure Alliance

GUIDELINES FOR PHARMACEUTICAL COMPANIES, SPONSORS, AND PRIVATE DONORS

As a non-profit organization, KCNQ2 Cure Alliance (KCA) is able to fulfill its mission and provide services free of charge through its fundraising and outreach efforts. KCA receives funding from diverse sources, including individuals, foundations, and health care-related corporations. KCA strives to avoid reliance on any particular source of funding, the loss of which could jeopardize the sustainability of programs and services.

KCA acknowledges the wide range of opinions regarding appropriate sources of funding for health advocacy organizations. In particular, some question whether it is possible for agencies like KCA, whose work is specific to KCNQ2-related disorders (KRD), to receive donations from corporations that benefit from the identification, treatment, or prevention of KRD without compromising positions on critical issues. Additionally, some question whether even the appearance of corporate influence is problematic.

KCA believes that corporations in the health space, including pharmaceutical corporations, are among the essential partners to engage. We are grateful that pharmaceutical corporations are willing to produce medications to treat KRD, and we cannot do this on our own without the involvement of such organizations. The role of new treatment options as a critical component of KCA care means that KCA must encourage and support their use. We must also address barriers to treatment that the KCNQ2 community may experience, including high drug prices, lack of and limited health care coverage, consumer cost-sharing burdens, and limits on access to patient assistance programs. Because KCA's work is driven by our mission, and not by our funders, the organization has on occasion lost corporate support due to positions on critical issues.

KCA believes it is ethical to encourage corporations (including those profiting directly from their work in KRD) to devote some of their profits and charitable contributions to support activities that benefit people at risk for and living with KRD and their families. Indeed, we believe they have a responsibility to give back in this way, particularly in a rare disease such as KRD where the burden of funding basic science research often falls on families who are already stretched thin.

To prevent real or perceived influence by any donors, KCA follows a policy of disclosure and transparency regarding its financial information, donors, programs, and advocacy positions. KCA also has written policies, authorized by its Board of

Directors, to govern its acceptance of donations from all donors, including corporate, foundation, government, and private donors. These policies include:

1. Donations to KCA are only used in the fight against KRD. KCA works to ensure that any donation will result in the maximum possible benefit to its constituents and the community, with the minimum possible administrative costs.

2. KCA solicits and accepts support only for projects and activities that are consistent with its Mission Statement, which has been previously reviewed and approved by the Board of Directors.

3. KCA maintains, at all times, an independent position on issues affecting the welfare of patients living with KRD. The interests of a donor or prospective donor are not a factor in KCA's decision-making process. The threatened or actual loss of funding will not dissuade us from taking public positions informed by our organization's values and mission.

4. On occasion, KCA will receive restricted donations from corporations, non-profits, foundations, and government entities. When it chooses to accept a restricted donation, KCA:
    a. Retains control over all aspects of the project;
    b. Ensures that the project meets a special, time-sensitive need of KCA or its constituents;
    c. Ensures that a written agreement regarding the restrictions is in place; and
    d. Ensures that the donation is used only for its agreed-upon purpose.

5. KCA reserves the right to announce all donations from corporate, nonprofit, foundation, and government sources, although it respects the rights of individual donors who seek privacy.

6. KCA does not allow donors to edit materials produced by KCA, including policy and program positions and press releases prior to their publication, except in the case of press releases specific to the granting of a donation. In turn, KCA may also ask for the opportunity to review drafts of similar materials or promotional pieces produced by donors.

7. To discourage the potential for or appearance of donor influence on programs, policies, or positions of the agency, KCA program staff are not involved in soliciting corporate, government, or non-profit foundation donations. Rather, program staff members are instructed to refer all such matters to the Executive Director.

8. As a matter of policy, the organization does not disclose its constituent mailing list for external use, nor is the list rented, lent, or shared to benefit constituents. Programs or services that may be of benefit to our patient community may be shared with constituents, at the discretion of the Executive Director and/or Board of Directors, in emails and/or newsletters that are distributed by KCA to our constituent mailing list.

9. KCA will provide a report of all donations of $100 or more on a yearly basis upon request. KCA also posts its annual tax returns (990s) on its website, www.kcnq2cure.org.

10. Members of the KCA Board of Directors and staff, as well as their immediate family, may not own shares of, or otherwise hold a direct financial interest in, any company whose primary focus relates to the diagnosis or treatment of KRD. They are permitted to own stock in larger pharmaceutical companies that serve both KRD and broader disease communities.

11. KCA does not elect members of the Board of Directors who are employees of pharmaceutical or diagnostics corporations that have products targeting KRD.

Guidelines for KCA-sponsored educational materials, trainings, and meetings

KCA's educational materials and training raise awareness of KRD health care, prevention, and treatment options among patients and families living with KRD, as well as health care and service providers. Our materials and trainings also provide guidance on actions these stakeholders can take to access health care and treatment options. Occasionally, KCA also holds meetings to address key questions arising from the issues in KRD. Given the important role these materials, trainings, and meetings play in improving access to prevention and treatment options, KCA staff and volunteers guarantee that:

1. The content of publications, meetings, and presentations is based on up-to-date, well-researched, and scientifically accurate information, presented in a balanced, objective manner, and not modified or influenced by corporate, government, non-profit, or other sponsors or donors.

2. There is full disclosure of any direct corporate, government, non-profit, or other support for particular publications, trainings, and meetings. In the case of meetings, the disclosure is made in invitations to participants, at the meeting, and in any reports produced regarding the meeting.

3. There is disclosure of any guest presenter's financial relationship to any company that produces any drugs or therapies discussed at the meeting by the presenter.

4. KCA encourages informed decision-making by patients and constituents regarding all aspects of their health and health care.

To that end, KCA provides information about specific products (including risks and benefits) and vendors available to address KRD. KCA does not promote the use of specific products or vendors. In limited cases, KCA may educate constituents about an evidence-based health care action when only a single product or vendor is available, but it will not promote the product itself.

Guidelines for participation in hearings

In our role as a health care and treatment advocate, KCA staff and volunteers are often called upon to provide testimony at public hearings and in various stakeholder and advisory groups. KCA will not receive donations from corporations with a vested interest in the results of a hearing in order to ensure attendance at the hearing by staff or volunteers, or to direct the testimony or input provided by staff or volunteers.

Guidelines for co-sponsorship of, participation in, or presentation at conferences, meetings, or other educational activities initiated by others

As KRD advocates and educators, KCA and its staff and volunteers are often asked to co-sponsor, participate in, or present at conferences, meetings, or other educational activities initiated by others. The purpose of attendance at such a meeting or event is to benefit KCA's constituents in the form of information or advocacy. For these activities:

1. Donors do not control the content of presentations made by KCA staff members or volunteers.

2. KCA may only accept reimbursement for reasonable travel, lodging, and meal expenses when necessary to support the participation of staff in a meeting that directly furthers our mission.

3. Any honoraria paid to staff members or volunteers for time required to participate in an invited meeting must be paid directly to KCA. In very rare instances, government committees or sponsors of events are not able to write checks of honoraria, per diem, etc. to KCA and must write a check to an individual. In these instances, the recipient must sign checks over to KCA and provide records related to the payment from the payee to KCA. If these payments have tax consequences for the staff member or volunteer, they will be permitted to keep a portion equivalent to the tax consequences, as verified by KCA's accountant.

Guidelines for acceptance of gifts to individual staff or volunteers from donors, including meals

With the exception of meals with a $75.00 limit as set forth below, no gifts or entertainment, including cash, may be accepted by KCA Board Members, staff, or volunteers from corporate donors.

KCA Board Members, staff, and volunteers may have meals paid for by donors in an amount not to exceed $75.00. They are also permitted to be reimbursed for registration fees or to accept waived registration fees for conferences or other events where they are presenting or will be volunteering their services on behalf of the KCNQ2 community.