



*One World, One Family, One Hope*



Melinda Riccitelli, Ph.D., President

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## CONGENITAL CENTRAL HYPOVENTILATION SYNDROME NETWORK EXHIBIT [\_\_] – POLICIES GOVERNING RESEARCH GRANTS

**About Congenital Central Hypoventilation Syndrome Network (CCHS Network):** The purpose of CCHS Network is to assist each other, and new CCHS families, in coping with issues that arise in living with a family member who is technology (ventilator) dependent and whose health status must be regularly monitored. Educating families and medical professionals about CCHS and supporting related research are principal purposes of the CCHS Network. The CCHS Network funds innovative clinical, basic translational or epidemiological research that will significantly impact the lives of patients with CCHS and advance the field of CCHS research generally. As a non-profit corporation, CCHS Network has been granted an exemption from Federal Income Taxes under Section 501(c)(3) of the Internal Revenue Code. Contributions to CCHS Network are tax deductible.

CCHS Network is an equal opportunity organization. No person is excluded from employment, membership on its governing body or research support due to race, religion, sex, national origin, age, or physical handicap.

**Award Goals and Scope:** The purpose of the CCHS Grant Award is to encourage and support high quality research that will result in a better understanding of CCHS or improve the lives of CCHS patients and families.

Applications are sought proposing novel approaches to the prevention or management of congenital central hypoventilation syndrome (including complementary, integrative or alternative approaches). The research strategy section of the application should list the specific aims, background and significance, as well as a detailed methodology/approach for (i) investigations related to the CCHS young adult population; (ii) any potential development of innovative technology or treatment modalities; and/or (iii) any basic/translational research in CCHS biology. The application should also (i) detail alternative strategies that may be utilized to overcome potential problems; (ii) present benchmarks and metrics of success; and (iii) describe future directions. These features of the proposal will be important considerations during the review process.

**Support:** Grant Awards will be made for a one-year period. Such awards will be limited to an annual maximum of \$\_\_\_\_\_ in direct costs (to be decided each year), with a subsequent maximum of \$10,000 portioned for equipment. For the avoidance of doubt, indirect and overhead costs are not permitted. Budget requests must be carefully justified and commensurate with the needs of the project.

**Involvement of Industry and Other Funding Agencies:** The active participation of industry and other funding agencies may be required for certain projects. CCHS Network recognizes this and will evaluate how such involvement facilitates the work being proposed on a case-by-case basis.

**Eligibility Requirements:** Applications may be submitted by individuals possessing a doctoral degree (including PhD, MD, DO, DC, ND, DDS, DVM, ScD, DNS, PharmD, or equivalent) in a related field and having a faculty appointment, or equivalent, with a 501(c)(3) institution (or equivalent non-profit organization), such as a university or college, with a demonstrated institutional commitment to the Principal Investigator (e.g., research lab space, clinical studies support, etc.). Junior faculty, post-doctoral fellows and residents are also eligible to apply; provided, a mentoring team is designated (strong support letter required). Applicants need not be U.S. citizens, and there are no restrictions on applicant age, race, gender or creed.

**Review Procedures:** Scientific peer review is conducted by the CCHS Research Advisory Board (RAB), comprised of (i) researchers and physicians respected for their accomplishments and expertise in the care of CCHS patients and the biology of CCHS; and (ii) parents and family members of CCHS patients who have a medical or scientific background, according to the Review Criteria summarized below. The RAB will also provide final approval of Pilot Grant Awards and funding determinations.

The RAB will review applications, as necessary, upon the decision to offer a Grant Award. If any application does not meet the program goals/scope, it will be administratively disqualified. Applicants selected for final funding will be notified as soon as possible. *Funding status is relayed by mail only and is not available by telephone.* All scores are considered confidential and are available to CCHS Network only. *Written critiques of the applications are not provided to applicants.*

**Review Criteria:**

The following criteria will be taken into consideration when assessing grant applications:

**Investigator(s)**

- What training and experience does the applicant and the research team have to ensure successful implementation of the proposed research?
- Track record and productivity of the investigative team will be assessed.

**Significance**

- Will the proposed work make a significant impact in the understanding, treatment, or care of CCHS patients?
- What potential will the research have to advance the field of CCHS research?

**Approach**

- Are the overall strategy, experimental design, and methodology well-reasoned and appropriate to achieve the proposed specific aims of the project within the grant term?
- Are potential problems and alternative strategies described?

- Are benchmarks and metrics of success presented?
- Is the budget fully justified for the proposed project?

#### Institutional Environment

- What institutional resources (e.g., equipment, core facilities, support, collaborators, etc.) are available to the applicant?
- Are such resources adequate to facilitate and successfully complete the proposed project?

**Funding:** The funds awarded shall be used solely for the purposes specified in the application submitted to CCHS Network, as executed by the investigator and institution and in strict compliance with the detailed budget affixed thereto, or any subsequent budget approved by the RAB. Funding of all grants is contingent upon final execution of the Grant Agreement by CCHS Network. All grant payments will be made through an invoice and reimbursement process.

Upon the effectiveness of the start date and throughout the duration of the Grant Term, the investigator and the Grantee Institution (together, the “Grantees”) may incur expenses related to the project, as permitted pursuant to these Policies. Upon the incurrence of such permitted expenses, the Grantees will submit original, itemized receipts (the “Invoices”) to the RAB for review and approval. Upon the approval of such Invoices by the RAB, the Grantees will be notified, in writing, and the relevant reimbursement will be dispersed directly to the Grantee Institution within thirty (30) days of such written notification.

The failure of the Grantees to adhere to any of the terms and conditions in the Agreement shall constitute sufficient grounds for CCHS Network, in its discretion, to terminate funding. In the event funding is terminated due to a breach under Section 5(c) of the Agreement, or any of the events referenced in Section 5(d) of the Agreement, the Grantees shall provide CCHS Network, on or prior to the thirtieth (30<sup>th</sup>) day after the early termination date, (i) Invoices for any unpaid expenses incurred prior to the early termination date that were not in connection with and subsequent to any breach under Section 5(c) of the Agreement or any of the events referenced in Section 5(d) of the Agreement; and (ii) reimbursement for the full amount of funds granted during the Grant Term that were expended in connection with and subsequent to any breach under Section 5(c) of the Agreement or any of the events referenced in Section 5(d) of the Agreement. Any reimbursements owed to the Grantees by CCHS Network, as reviewed and determined by the RAB with written notification of approval to the Grantees, will be distributed within thirty (30) days of such written notification.

*CCHS Network grants do not constitute an employer-employee relationship between any of the Grantees and CCHS Network.*



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*CCHS Network does not assume any legal responsibility or obligation for the conduct or actions of the Grantees.*

**Identification:** The title “CCHS Network Research Fellow” shall be used in all publications during the Grant Term. Identification with CCHS Network shall also be made in any news releases about the recipient or the Research Project by the public relations department, or its equivalent, at the Grantee Institution.

**Reinstatement of Funds:** Funds will not be reinstated after CCHS Network has received written notification from the Principal Investigator of his or her intent to terminate the grant. Those wishing to resume funding are welcome to submit a new application which will compete on an equal basis with all others at the RAB’s next applicable review meeting.

**Transfers:** In the event the Principal Investigator desires to transfer to another Grantee Institution while the grant is in effect, continuation of the funding at a new Grantee Institution may be permitted; provided, the Principal Investigator provides sixty (60) days prior written notice to, and receives written approval from, the RAB. The decision to approve the transfer will be at the RAB’s sole discretion.

**Leave of Absence:** Written permission must be obtained from the RAB if a grant is to be interrupted and continued at a later date. Permitted leaves of absence are limited to six (6) months.

**Reallocation of Funds:** The Grantees will be permitted to reallocate up to fifteen (15) percent of the total fund across budget line items at their discretion and without a formal request to the RAB; provided, such funds are used exclusively for purposes within the permitted scope of the Research Project. Notwithstanding the foregoing, funds may not be moved across budget line items, if the result exceeds any maximum allowable cost set for a budget line item (*e.g.*, equipment). Any movement of more than fifteen (15) percent of total grant funds across budget line items must be requested by the Grantees, in writing, and approved by the RAB. Such written request should be submitted directly to the RAB, specifying the amount to be reallocated, which line items are involved, the reason for the allocation and any other details pertinent to the reallocation. The RAB, in its sole discretion, may deny any Invoice for expenses incurred that result in a movement of more than fifteen (15) percent of total funds across budget line items without the prior approval of the RAB.

**Scientific Progress Reports:** The Grantees must submit one (1) typewritten scientific progress report no later than six (6) months after the effective date of the Grant Term. The scientific progress report should include a summation of the research conducted to date, together with copies of any and all publications concerning said research, as well as any requisite notifications regarding patent applications (described further below). As part of this report, there must be a one-paragraph summary drafted for the lay public.

Scientific progress reports that are more than thirty (30) days late will result in suspension (or possible termination) of funds. These reports shall be reviewed by the RAB in order to evaluate the research progress of the Grantees. CCHS Network reserves the right to terminate any grant if the RAB determines in its sole discretion that the Grantees have failed to make adequate progress on the Research Project.

**Financial Reports:** The Grantees must submit one (1) typewritten financial report no later than six (6) months after the effective date of the Grant Term, detailing how the funds were expended to date.

**Scientific Progress and Financial Final Reports:** On or prior to the thirtieth (30<sup>th</sup>) day after the termination date or early termination date, as applicable, the Grantees shall provide (i) a final scientific report; and (ii) a final financial report. The final scientific report should include a summation of the research, together with copies of any and all publications concerning said research, as well as any requisite notifications regarding patent applications (described further below). Again, a one-paragraph summary of the Research Project must be included for the lay public.

CCHS Network may contact the Principal Investigator for up to two (2) years after the termination of the Grant Term, to determine (i) how the funding provided influenced his/her career; (ii) how it may have contributed to improving the quality of life of patients with CCHS; and (iii) how it may have advanced the field of CCHS research.

**Human Investigation:** If any research or activity conducted in connection with the Research Project may involve human subjects, the Grantees must obtain approval by an Institutional Review Board (IRB) or international local ethics board equivalent. The Grantees must submit an original executed copy of such approval to the CCHS Network prior to such research or activity. Failure to notify CCHS Network of the use of human materials or subjects for purposes of the Research Project may result in suspension or termination of the grant.

**Laboratory Animals:** If any research or activity conducted in connection with the Research Project may involve animals, the Grantees must obtain approval from an Institutional Animal Care and Use Committee (IACUC) or international animal welfare board equivalent. The Grantees must submit an original executed copy of such approval to the CCHS Network prior to such research or activity. Failure to notify CCHS Network of the use of animals for purposes of the Research Project may result in suspension or termination of the grant.

**Deadlines:** CCHS Network Pilot Grant Award application deadlines and award announcement timing will be conveyed in the relevant Call for Applications issued by CCHS Network from time to time.



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**Confidentiality:** All application evaluations are considered confidential and are only available to the CCHS Network.

**Applications:** CCHS Network does not accept unsolicited grant applications.