

## **CLINICAL RESEARCH AWARD (CRA)**

### **Application Guidelines for 2025 CRA Cycle**

The Children's Tumor Foundation (CTF) is dedicated to funding and driving innovative research that will result in effective treatments for all patients with neurofibromatosis, including neurofibromatosis type 1 (NF1) and all types of schwannomatosis (NF2-related schwannomatosis (NF2-SWN) and/or non-NF2 related schwannomatosis (non-NF2 SWN)).

CTF's Clinical Research Award (CRA) program is focused on supporting the investigation of new treatments or interventions with the goal of improving health outcomes and the management of patients with NF. NF affects all populations equally, and while there is no cure yet, CTF's mission of driving research, expanding knowledge, and advancing care for the NF community fosters our vision of ending NF.

#### **PROGRAM FOCUS**

The Clinical Research Award (CRA) program aims to advance the development of effective clinical treatments, interventions, and management of patients living with NF.

Priority consideration will be given to proposals that:

- Investigate bold, forward-thinking solutions and treatments that could improve the everyday functioning of people with NF.
- Promote new directions for disease management that would likely progress to future large-scale studies with the potential to compete for additional external funding.

Proposals can include but are not limited to:

- Prospective or retrospective clinical studies
- Pilot clinical trials
- Correlative investigations adjunct to an ongoing clinical trial.
- Biomarker studies (e.g. molecular, imaging, or genetic biomarkers) that may help to diagnose, monitor or prevent disease.
- Patient-reported outcome measures or other real-world evidence that can assess disease burden, risk stratification, short- or long-term treatment effects, etc., for specific manifestations
- Observational studies to include natural history/real world evidence, and clinical heterogeneity and its relation to genetics, environmental, or biologic factors

#### **COMMITMENT TO OPEN SCIENCE AND DATA SHARING**

CTF values the open sharing of research outputs and since 2018 has funded the NF Data Portal, a public data repository that stores and shares data generated by multiple collaborative research programs focused on NF diseases (neurofibromatosis and schwannomatosis).

By applying to any CTF grant, applicants agree to the principles of the NF Open Science Initiative (NF-OSI), an open effort focusing on finding NF treatments by sharing data and analysis results with the broader community. Please read more about our commitment to open science and data sharing [here](#).

### **APPLICANT ELIGIBILITY**

- Applicants should have an MD or PhD or other advanced degree from a recognized US or non-US institution.
- There is no citizenship requirement. Applications are welcome from qualified individuals worldwide.
- Applications are welcome from both academic and private sectors.
- CTF requires all applicants to acquire a personal ORCID ID (<https://orcid.org/>) and to elect CTF as a trusted partner on ORCID. Once an applicant has granted permission, CTF as the trusted organization will be able to see information that they have set as visible to trusted parties in addition to the information set as visible to everyone. Please visit this ORCID page to learn more about visibility settings and trusted organizations. Since ProposalCentral has developed an extended integration with ORCID to allow seamless data transfer, applicants are strongly encouraged to keep their ORCID ID record up to date especially in the Education, Funding and Works (publications) sections.
- New submissions from current or past grantees are welcome at every CRA cycle. Recipients of past or current grants may submit a new proposal or a proposal for a funded extension of a current study for a maximum of 2 consecutive cycles (in the case of extensions). Applications for funded grant extensions will be reviewed, scored, and recommended for funding together with all other submissions for that cycle.
- Existing grant timelines cannot overlap with new grant request timelines.
- Grantees may request a 1 year no-cost extension at the end of the initial grant period.

## **AWARD DURATION AND FUNDING**

The CRA program provides funding for TWO YEARS. Funding requests have a maximum of **\$200,000** total for the entire two-year period and is INCLUSIVE of up to 10% indirect costs. Payments will be disbursed throughout the award period at 6-month intervals and may be contingent on receipt of satisfactory progress reports.

Award activation requires that the CTF Award Letter, Patent Policy, Award Contract, and a data sharing plan are signed, and that the study has been IRB-approved (Note: IRB approval is not required at the time of application but is a must if the proposal is selected for funding). Please see the Award Activation section of the Terms of the Award below for more information.

## **APPLICATION PROCESS**

The CRA application process comprises two stages, which will be executed through the ProposalCentral grants management platform. Stage 1 is the Letter of Intent (LOI) or pre-application outlining the proposed project and its key aims. LOIs will be reviewed by the CRA program committee. Those meeting criteria will be invited to submit a full proposal (Stage 2).

To start your application in ProposalCentral, type the foundation's name in the search box. Select Children's Tumor Foundation Clinical Research Award and click "Apply Now."

### **Stage 1 - Letter of Intent:**

The Letter of Intent is an online form and below are some of the important sections -

- Project Details
  - Hypothesis and aims of the study (4000 characters)
  - Overview of the study design (4000 characters)
- Research significance
  - Filling a gap in NF research (2500 characters)
  - Impact on NF patients (2500 characters)
- Budget Summary
- Organizational Assurances

### **Stage 2 - Full Application:**

Applicants invited to submit the full application will be asked to provide -

- **Lay Abstract** - *Entered directly in the application form on ProposalCentral.*

Maximum of 2500 characters.

- **Scientific Abstract** - *Entered directly in the application form on ProposalCentral.*

Maximum of 2500 characters.

- **Research Plan** - *To upload on ProposalCentral.*

The Research Plan (6 pages max, single line spacing, Calibri size 11 font) must include

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- Introduction and aims of proposed research
- Research design and methodology
- Milestones and timelines, summary of available resources
- Significance of proposed research, how it advances the development of effective therapies or care for NF patients and what you envision as possible future directions for this work

- **Citations** - *To upload on ProposalCentral.*

All relevant literature is cited in a separate document that is uploaded separately.

- **Open Access Research Output** - *Entered directly in the application form.*

In addition to the requirement of key data sharing described below, CTF values the open sharing of research outputs such as open access articles, open access books, book chapters, and/or monographs, copies of your papers, chapters, monographs, or other published materials in institutional or disciplinary repositories, preprints, datasets, software/code, materials/reagents, preregistration plans, public disclosure of negative results, and any other outputs, and encourages all its awardees to make all research outputs publicly available.

To evaluate an applicant's willingness to openly share research outputs, we ask applicants to provide representative examples demonstrating how they have made outputs from other projects openly accessible. Please also provide, where possible, the DOI and license terms that facilitate access and reuse of these materials. Please know that not having prior open access research outputs does not exclude your application from receiving a fair review.

- **Biographical Sketch** - *A NIH biosketch template will be provided in the application form.*
- **Budget Justification** - *Budget template will be available in the application form.*

- **Commitment to submit a Data Sharing Plan** - CTF template will be available in the application form

CRA recipients are required to upload annotated key data generated under their grant in the NF Data Portal where the data will be embargoed for a maximum of 12 months following project completion. Applicants are not required to identify such key data upon application. However, grant disbursement of successful applications will be contingent on such key data being identified in the Data Sharing Plan described below and to the upload of correctly annotated data. Please see the Award Activation section below for more information.

- **Patent Policy** - CTF template will be available in the application form

Applicant institutions are strongly recommended to sign the CTF Patent Policy at the time of application submission in order to speed up the process of award activation. Please see the Award Activation section below for more information.

## REVIEW PROCESS

All applications will be reviewed by the CTF CRA Program Committee, external reviewers, and NF patient/caregiver reviewers where necessary. A statistical review of the experimental protocol will be included for applications as needed. Reviewers will consider, in order of importance:

1. Impact of proposed research
2. Feasibility of proposed research
3. Transparency/soundness of experimental protocol
4. Appropriateness of budget
5. Applicant qualifications
6. Open science/data sharing readiness

Other factors influencing the review include: Applicant's interest in, and potential for, a research career in NF, strength of program of sponsor and institution, appropriateness of budget/budget justification, and recruitment of subjects from diverse backgrounds and underserved communities.

The review panel will select and recommend applications for funding. Final funding of awards is approved by CTF's Research Advisory Board, Medical Advisory Committee, and Board of Directors and is based on review scores as well as availability of funding. No funding decision will be final until approved by the Board of Directors. All awards are subject to CTF application guidelines, regulations, and policies.

## NOTES:

1. NF patient/caregiver reviewers, when used, will review and score only specific sections (lay abstract, impact of research on NF patients) of the application. Their score and statistical review score will be integrated into the final application score.
2. Based on reviewer feedback, CTF may request the applicant to revise the application and resubmit for review.
3. Open science/data sharing readiness is considered a plus.

## TERMS OF AWARD

### I. Applicant Notification

Applicants will be notified about the decision on their application within 6-8 weeks after their full application submission. All applicants, both funded and not funded, will be provided with a summary of the feedback from the review of their application.

### II. Award Activation

Applicants whose proposals are selected for funding will be requested to complete and return the following documentation to CTF before their CRA award can be activated –

- **Acceptance of Award** – An award acceptance letter will be emailed requesting information on Awardee, Institution, contact officials, and bank information for electronic **transfer of payments**.
- **Data Sharing** – Awardees will be required to complete CTF's [Data Sharing Plan](#) and register their project as a new study on the [NF Data Portal](#). For more information about the data sharing process, please visit [this](#) page on the NF Data Portal.
- **Patent Policy\*** – Awardee institutions will be required to sign CTF's [Patent Policy](#) before the award can be fully activated. We strongly recommend signing the Patent Policy at the time of application submission in order to speed up the process of award activation. If your institution is not able to agree to the terms of the Patent Policy as they stand, please contact us as soon as possible at [ctfgrants@altum.com](mailto:ctfgrants@altum.com). The Patent Policy is intended to ensure that any inventions or patented technologies arising from CTF-supported research are commercialized where possible. CTF anticipates recouping some revenues arising from commercialized technologies it supported, in proportion to the contribution made by CTF's initial funding. Such funds will be used to support further initiatives at CTF.

**\*Special Note to Federal Employees (e.g. NIH intramural researchers)**

Since the National Institutes of Health are prohibited by congressionally enacted federal law from accepting the terms of CTF's Patent Policy, the policy may be waived for federal employees, such as NIH intramural researchers, depending on the project being funded. Federal employees wishing to apply for a grant are, therefore, invited to discuss their project with CTF prior to submitting their grant proposal. Any information shared with CTF will be treated confidentially.

### **III. Status of Awardee**

The Awardee shall be considered an employee of the awardee's institution and not of CTF.

### **IV. Extended Leave of Absence**

Should the awardee need to take a leave of absence for more than a month for reasons such as maternity/paternity or illness, CTF must be informed of the date of departure and expected date of return.

### **V. Award Purpose Change or Transfer**

Any fundamental change in the purpose for which the CRA was originally made must have prior written consent of CTF. A CRA may not be transferred from one institution to another without prior written authorization from CTF.

### **VI. Award Cancellation or Early Termination**

CTF reserves the right to cancel or prematurely terminate a CRA if required. In such an event, the award amount will be prorated based on the number of months it was in effect. A final report of expenditures and a refund of any unspent funds must be submitted to CTF within 60 days after cancellation or termination. Failure to provide the final expenditure report by the required date will result in suspension of the award and may impact the applicant's eligibility for future funding opportunities at CTF until all materials are received.

### **VII. No-Cost Extension**

CTF allows awardees to request a No-Cost Extension (NCE) of the final budget period of their award for up to 1 year beyond its original expiration date. All terms and conditions specified in the original contract will apply during the extension period. Upon notification of approval by the CRA program committee, CTF will revise the project end date and provide an acknowledgment to the awardee.

### **VIII. Other Sources of Support**

Research overlap with other proposals is permitted as long as CTF is advised. The awardee and

the sponsoring institution are responsible for informing CTF of possible conflicts related to duplicate funding of the CRA-funded project. Failure to inform CTF of other sources of support can result in loss of CTF funding and may also impact the applicant's eligibility for future funding opportunities at CTF.

### **IX. Periodic Reporting**

Awardees are required to submit two types of reports periodically through their account on ProposalCentral:

- Progress report
  - A detailed update on the development of the CRA-funded research must be provided to CTF at 6, 12, 18, and 24 months after activation of the award.
- Financial report
  - An expenditure update vs budget must be provided within 60 days after completion of the award.
  - All expenses must be reported in US dollars only.
  - Financial report must be signed by the institution's financial officer.
  - Any unexpended and uncommitted funds in possession of the awardee at the end of the award period must be returned to CTF within 60 days from the expiration of the award.
  - In addition to the above, interim accounting may be requested by CTF.

Awardees will be provided with a schedule of payments and reporting dates in the award letter. Templates and instructions for these reports will be made available.

### **X. Public Notification of Awards Funded**

Once the CRA is activated, CTF will advertise online and in its other public documentation the recipients of the CRA together with a lay summary of the proposed research. Please include a photograph of yourself (over 2MB) that we can use in upcoming award announcements.

### **XI. Publicity, Publications or Exhibits Notification of Awards Funded**

The Awardee Institution must notify CTF in advance of any publications, presentations, or announcements pertaining to work done under the Award, or Follow-Up Work, whether these are to professional audiences or the public media. For professional publications and presentations, once these have been accepted, the Awardee Institution must submit an electronic copy of the paper, abstract, slide presentation, or poster to [ctfgrants@altum.com](mailto:ctfgrants@altum.com) with

details of publication release or presentation (journal, meeting, time, location). The support of



CTF must be duly recognized everywhere, and must include the CTF grant number and Digital Object Identifier (DOI).

For announcements to the public, the public media and/or the press, including a posting to the Internet, pertaining to this Award or any Follow-Up Work (collectively, a “Release”), Awardee Institution agrees to provide a draft of such Release to CTF at [media@ctf.org](mailto:media@ctf.org) at least one week before such publication of such Release so as to provide CTF the opportunity to suggest edits to the language of the Release, particularly as to CTF’s role in the Award, any Follow-Up Work, and neurofibromatosis research. Awardee Institution agrees to consider all such suggestions and include them in the Release if they are accurate. Awardee Institution shall not unreasonably decline to include any edits in a Release.

For the purposes of this Award, the term, “Follow-Up Work” shall mean any research predicated upon or directly related to the research funded by this Award.

## **XII. Open Access Fee Reimbursement Policy**

CTF encourages and enables its awardees to publish in open access journals, which facilitates more rapid dissemination and broad use of their publications. To do so, we have established an annual fund that is available on a first-come, first-served basis to current awardees to pay the fees incurred for publishing in open access journals.

- The publication must be based on CTF-funded research.
- Requests must be submitted during the award period, or within 18 months of the award end date.
- Awardees should submit a written request to [grants@ctf.org](mailto:grants@ctf.org) with 1) a copy of the invoice or receipt for publication fees from the journal, 2) PDF copy of the accepted publication, and 3) active URL link to the publication.

All requests will be reviewed, and if approved and if there are funds remaining, the publication fees will be duly reimbursed. If not available, authors are encouraged to explore “green open access” as a repository-based open access option within their institution.

## **XIII. Follow-On Funding**

Awardees are required to keep CTF informed about any follow-on funding, collaborations, and publications (posters, papers) generated from the research funded by the DDI. Such continuing communications will allow CTF to measure the impact of its research funding more easily.

Please email [ctfgrants@altum.com](mailto:ctfgrants@altum.com) if you have any questions. We wish you the very best and look forward to receiving your application.