CLINICAL RESEARCH AWARD

Application Guidelines

The Children’s Tumor Foundation (CTF), founded in 1978 as the National Neurofibromatosis Foundation, is a non-profit organization committed to identifying effective therapies for neurofibromatosis (NF), which includes NF1, NF2, and schwannomatosis, and to improving the lives of those living with these disorders. NF1 is one of the most common rare diseases, affecting 1:3,000 individuals (around 100,000 persons in the US and over 2 million worldwide). Since its inception, CTF has committed over $50 million to research grants and initiatives, supporting scientists around the world to conduct groundbreaking NF research.

NF causes a range of central and peripheral nervous system tumors (benign and malignant), bone abnormalities, learning disabilities, pain, vascular complications, and other manifestations. The progress of NF is unpredictable and often presents a lifelong burden to the affected person. Other than the recently approved Koselugo (selumetinib) for pediatric NF1 plexiform neurofibromas, there are no effective drug therapies for the diverse manifestations of NF. The Clinical Research Award (CRA) program supports the development of both drug and other therapeutic modalities, such as psychosocial interventions. The signaling pathways affected in NF are common to other disorders, so NF clinical research promises wider applications.

DEI Statement

CTF is committed to fostering, cultivating, and preserving a culture of diversity, equity and inclusion. We embrace and encourage our applicants differences in backgrounds, experiences, race, color, religious creed, sex, national origin, ancestry, citizenship status, family or marital status, physical, mental and/or intellectual abilities, age, military or veteran status, registered domestic partner or civil union status, gender and gender identity, sexual orientation, political affiliation, and socioeconomic status.

PROGRAM FOCUS
The purpose of the CRA is to advance effective clinical therapies for NF by supporting early-stage investigations of broad-thinking, novel ideas involving candidate therapeutics, neurocognitive or psychosocial interventions, and clinical-trial-enabling studies. Examples of areas of interest for this award include, but are not limited to, the following:

- Pilot clinical trials or studies adjunct to an ongoing clinical trial
- Biomarker studies (e.g. molecular, imaging, or genetic biomarkers) that may inform or accelerate a clinical trial or the development of diagnostics
- 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
- Natural history
- Clinical heterogeneity and its relation to genetic, environmental, or biologic factors
- Adult care concerns such as barriers to care, transition from pediatric to adult healthcare, chronic pain management, mental health, nutrition, bone/joint health, and sexual and reproductive health
- Research in support of developing evidence-based care and treatment guidelines

**COMMITMENT TO OPEN SCIENCE AND DATA SHARING**

The Children’s Tumor Foundation values the open sharing of research outputs and in 2018 funded the [NF Data Portal](https://nfdataportal.org), a public data repository that stores and shares data generated by multiple collaborative research programs focused on neurofibromatosis (NF) diseases (neurofibromatosis type 1, type 2, and schwannomatosis).

By applying to any CTF grant, applicants agree to the principles of the [NF Open Science Initiative](https://nfosi.org), an open effort focusing on finding NF treatments by sharing data and analysis results with the broader community. If your IRB or institution does not permit sharing of de-identified data, or if for other reasons you are unable to share such data, you must provide an explanation and supporting evidence.

Please read more about our commitment to open science and data sharing [here.](https://nfosi.org)
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 (ORCID) 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 visible to everyone. Please visit the ORCID page to learn more about visibility settings and trusted organizations. Since ProposalCentral (platform used for CTF grant management) 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 $150,000 total for the entire two-year period. Please note this funding amount is INCLUSIVE of up to 10% indirect costs.

Payments will be disbursed throughout the award period at 6-month intervals, with 50% of Year 1 funds released at activation of award. Following payments are contingent on receipt of satisfactory progress reports every 6 months following initiation of award.
Award activation requires that the CTF Patent Policy and the Award Contract are signed, and that the study has been IRB-approved. Please see the Award Activation section of the Terms & Conditions below for more information.

**Direct costs**
Up to $1,500 to support travel to an NF-related meeting
Salaries for researchers (percentage)
Research supplies
Research-related subject costs
Support for multi-disciplinary collaborations
Biostatistical support (recommended)

**Indirect costs**
Indirect costs are items such as overhead, administrative, and facility costs that are not readily identifiable with the project, but are nevertheless necessary for general operation.

**APPLICATION PROCESS**

The CRA application process comprises two stages, which will be executed through the ProposalCentral grants management platform (Proposal Central: Altum). 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 Proposal Central, type the foundation's name in the search box. Select Children’s Tumor Foundation Clinical Research Award and “Apply Now.” Forms can be downloaded from the site for offline use.

**Stage 1 - Letter of Intent (Pre-Application):**

These sections appear in the online LOI form:

- **How will this project fill a gap in NF research?** (up to 2,500 characters)
- **How will this research impact patients?** (up to 2,500 characters)
- **Project Details** (literature cited should be uploaded separately as an attachment).
  - Hypothesis and aims of the project (up to 8,000 characters).
  - Overview of the study design including anticipated timeline (up to 8,000 characters)
Lay Abstract (up to 2,000 characters)
Scientific Abstract (up to 2,000 characters)
Keywords, Study Type, Research Areas
Budget Summary
Organizational Assurances

**Stage 2 - Full Application:**

These sections appear in the online full application form:

**Download Templates and Instructions**

- Application Guidelines
- Research Proposal – *Instructions; upload as Attachment. 6 pages excluding references.*
- Biographical Sketch - Principal Investigator (*Template; upload as Attachment*)
  *Applicants can also upload a biosketch generated through SciENcv.*
- Biographical Sketch - Other/Key Personnel (*same template as above*)

**Enable Other Users to Access this Proposal**

**Organization/Institution & Contacts**

**Key Personnel**

**Abstracts and Keywords** - *Enter directly in the application form on ProposalCentral.*
(up to 8,000 characters per section)
  - Layman’s Summary for General Audience
  - Scientific/Technical abstract

**Budget Period Detail**

**Budget Summary and Justification**

**Other Support**

**Organizational Assurances**

**Publications**

**Proposal Attachments** - *Upload Research Proposal, References, Biosketches, Data Sharing information.*

**Data Sharing Plan** - At the proposal stage, applicants are not required to submit a full Data Sharing Plan (DSP), however in order to activate the award, applicants are required to submit either a Data Sharing Plan or an explanation of why this is not possible, for example, if your IRB or institution does not permit sharing of de-identified data, or if for other reasons you are unable to share such data. Please see the **Award Activation** section of the Terms & Conditions below for more information.
REVIEW PROCESS

All applications will be reviewed by the CTF CRA Program Committee, external reviewers, and patient reviewers where necessary. A statistical review of the experimental protocol will be included for all applications. 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; 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. Patient reviewers will review and score only specific sections (lay abstract, impact of research on NF patients) of the application. Patient’s 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
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** – CTF believes in making data from all its funded projects freely accessible irrespective of whether the findings were positive or negative. Awardees are strongly encouraged to complete a Data Sharing Plan and register their project as a new study on the NF Data Portal. At the proposal stage, applicants are not required to submit the full Data Sharing Plan (DSP). Applicants are strongly recommended to submit the complete DSP at the time of application submission in order to speed the process of award activation. Normally CTF allows for a 12-month embargo on the data from the end of the award after which the data will be opened to the community. For more information about the data sharing process, please visit the Help page on the NF Data Portal and the proposed standards for data sharing specifications doc.

- **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 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 grants@ctf.org. 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.

- **Expenditure report**
  - One expenditure update vs budget must be provided within 60 days after completion of the award.
  - All expenses must be reported in US dollars only.
  - Expenditure 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 grants@ctf.org 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 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 of $15,000 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 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 grants@ctf.org if you have any questions. We wish you the very best and look forward to receiving your application.