



Clinical Trials Program  
Request for Proposals

2019

## I. BACKGROUND

The Chordoma Foundation is a nonprofit organization dedicated to improving the lives of chordoma patients and leading the search for a cure. In service of this mission, the Foundation's Clinical Trials Program supports well-justified clinical trials designed to determine whether, and to what extent, promising new therapies can improve the lives of chordoma patients. The intention of this program is to eliminate the barriers that typically hinder clinical trials for rare cancers, ensuring that scientifically-sound treatment approaches are tested in chordoma patients as quickly as possible. The Foundation is currently supporting seven clinical trials, five of which are currently enrolling patients, and aims to initiate at least 10 clinical trials by the end of 2020.

## II. PURPOSE

Through this request for proposals, the Foundation aims to identify one or more new therapeutic concepts with strong scientific rationale. Selected trial concepts will receive support from the Foundation with the goal of opening trials in late 2019 to 2020.

## III. MECHANISM OF SUPPORT

- **Trial Initiation Assistance:** Assist with trial design, site recruitment, and/or applications for obtaining study drug, as needed.
- **Patient Education and Outreach:** Assist trial sponsor in raising awareness about the trial among the Foundation's extensive network of chordoma patients, caregivers and healthcare providers.
- **Funding:** Provide grants of up to \$300,000 to fund non-drug study costs of investigator-initiated trials.

## IV. KEY DATES

- Concepts due: May 10, 2019
- Applicants notified: July, 2019

## V. APPLICATION INFORMATION

Applications will be accepted from investigators at academic institutions, nonprofit research institutions and for-profit companies. To apply, complete the accompanying application form with all of the information requested. The application should be returned to Joan Levy, Director of Research, via email at: [joan@chordoma.org](mailto:joan@chordoma.org) no later than May 10, 2019 by 8PM EST. Applications arriving after this deadline will not be accepted for review. Inquiries concerning the application and process should also be directed to Joan Levy via email.

Proposals are reviewed in a three-stage process:

1. **Concept review:** CF Medical and Scientific Advisory Boards jointly evaluate the scientific and clinical rationale for the trial concept and recommend whether the concept merits the Foundation's support. The investigator may be asked to join the review committee meeting via teleconference to provide a brief concept overview and address any questions from the advisory board members.
2. **Protocol review:** If the concept is endorsed, investigators are invited to submit the full trial protocol for review and feedback from the Medical Advisory Board (MAB). Investigators will have the opportunity participate in a teleconference with the MAB to get feedback and answer questions about the protocol. The Foundation will provide investigators with written feedback from the MAB, including both recommended and required modifications to the protocol.
3. **Budget review:** Once the protocol is approved, investigators are invited to submit a request for funding, which is considered by the Foundation's Board of Directors. Note: approval of a trial concept and protocol does not guarantee funding.

## VI. CRITERIA FOR CONCEPT SELECTION

1. The Foundation aims to support proof of concept clinical trials designed to efficiently demonstrate an initial signal of clinical activity.
2. Priority is given to trial concepts for which the primary endpoint can be evaluated within two years of patient enrollment.
3. Trials may test single agents or combinations, including agents combined with radiation or other standard treatment modalities.
4. Agents may include approved drugs and/or experimental therapies.

5. Trials must be scientifically well-justified, supported by at least two of the following:
  - a. Strong mechanistic rationale relevant to chordoma
  - b. Strong preclinical activity in at least two chordoma preclinical models
  - c. Two or more documented cases of clinical activity in chordoma patients
6. Trial design, including objectives, endpoints, inclusion/exclusion criteria, treatment plan, and statistically-determined trial size, must be appropriate for the chordoma patient population.
7. Though important, the Foundation does not support observational or retrospective studies through this program.