CRI Cancer Research Institute™

Clinical Innovator Grant

Terms and Conditions

Upon activation of this grant, the applicant organization becomes a grantee and assumes legal and financial accountability for the awarded funds and for the performance of the grant-supported activities.

Certifications

- A written statement testifying to the following points must be submitted along with the signed Terms and Conditions:
  - Certification that the proposal has been reviewed and approved by the appropriate Institutional Review Board(s).
  - Certification that the clinical study will fully comply with Good Clinical Practices and all federal, state, and local laws, rules and/or regulations.
  - Certification that the applicant organization will not use the services of any individual who has been debarred under the Federal Food, Drug, and Cosmetic Act or excluded from receiving federal funds.
  - Certification that if any IND is required for the clinical trial, the applicant organization will obtain said IND approval by the relevant competent authority prior to the receipt of any grant funds. Proof of IND approval must also be submitted.
  - Certification that the applicant organization will maintain an appropriate electronic database with sufficient capabilities to capture expected data and outcomes contemplated in the protocol for the clinical study, including information regarding patient enrollment and adverse events, and references to an published abstracts and manuscripts.
  - Certification that the applicant organization has established and maintains appropriate policies and procedures for the protection of human subjects, and that the organization, whether domestic or foreign, bears the responsibility for safeguarding the rights and welfare of human subjects.
  - Certification that any research supported under this grant that uses recombinant DNA molecules complies with the regulations set forth for their use by the National Institutes of Health.
  - Certification that the applicant organization and its Investigators will not discriminate in the patient population according to race, creed, color, national origin, sex, or handicap.

- CRI indemnification and hold harmless agreement (see attached form), executed by the applicant organization indemnifying Cancer Research Institute (CRI) from any lawsuit or claim relating to the activities supported by this grant.

- An original signed Certificate(s) of Insurance evidencing that the applicant organization has obtained and maintains, in full force and effect, the following insurance during the term of the grants:
  - worker's compensation insurance in accordance with the statutory requirements in the state where the institution does business;
  - employers' liability insurance with a minimum limit of $1,000,000; and
  - comprehensive general liability coverage, with a minimum limit of $2,000,000 combined single limit per occurrence.

  The Certificate(s) must provide that thirty (30) days' prior written notice of cancellation of the insurance policy be given to the Cancer Research Institute.

Financial

- Payments will be made to the sponsoring institution based on the trial achieving the milestones set forth below. Principal Investigator is expected to promptly notify CRI when trial milestones are achieved.

- Milestones:
  - Contract execution and IND approval (20%)
  - First Patient First Visit (20%)
  - 50% of patients enrolled (20%)
  - Last Patient Last Visit (20%)
  - Receipt of final Clinical Study Report (10%)
  - Receipt of final translational study report (5%)
  - Receipt and approval of data deposition plan (5%)

- Deductions for administrative overhead or indirect costs of any kind are not permitted.

- Unexpended funds may be carried over from one year to the next. Any remaining balance at the end of the grant must be returned to the Cancer Research Institute within 30 days of termination of the award unless a no-cost extension is requested and granted.

Progress Reports and Reports of Expenditures

- Grantees are expected to have and maintain access to CRI's Grantee Portal: http://www.grantrequest.com/SID_2015

- Milestone payments are based on investigators providing CRI with timely updates that such milestones have been achieved. These updates are to be provided through CRI's online grantee portal.

- Following the start of the translational study, annual scientific progress reports are expected until the completion of the study. These reports are to be submitted through CRI's online grantee portal.

- The institution must submit annual expenditure reports detailing the usage of the awarded funds during the previous 12 months. Expenditures are to be reported in direct comparison to the budget provided in the original application form. Reports should also provide an explanation for any projected changes to the budget going forward. Fund balances may be carried over into the next award year, but any balance remaining at the end of the entire support period must be returned to CRI unless administrative extension has been requested and approved. Expenditure reports should be submitted through CRI's online grantee portal.

Data Sharing Policy

- By implementing this data sharing policy, CRI aims to accelerate research progress and improve patient outcomes by enabling broad and transparent sharing of clinical trial data. Recipients of a Clinical Innovator grant are required to deposit their research data into the Cancer Research Institute's iAtlas platform within six (6) months of publication of their research results. Grantees must deposit their clinical trial data in a format that is machine-readable, standardized, and compatible with the iAtlas platform. Grantees must work with the iAtlas team to provide adequate documentation and metadata to enable data to be incorporated into the platform. Any restrictions on data sharing, such as concerns related to patient confidentiality or intellectual property must be communicated with CRI and the iAtlas team as soon as possible.

Publications and Acknowledgement

- Cancer Research Institute funds biomedical research in order to better understand the causes of cancer and to advance its prevention, diagnosis, and treatment. The main output of this research is new knowledge. To ensure this knowledge can be accessed, read, applied, and built upon in fulfillment of our goals, CRI expects its researchers to disseminate their findings, including publishing in peer-reviewed journals.

  In addition, it is a condition of CRI funding that all peer-reviewed articles supported in whole or in part by its grants must be made available in the PubMed Central online archive. PubMed Central is a database of full-text biomedical journal articles available online without a fee, hosted by the National Library of Medicine in the National Institutes of Health. Once posted in PubMed Central, results of research become more accessible, prominent, and integrated, making it easier for scientists worldwide to pursue biomedical research. It also makes this information accessible to CRI and its donors, as well as patients, clinicians, educators, students, and others.

  CRI award recipients are required to deposit an electronic copy of their final peer-reviewed manuscripts in PubMed Central immediately upon acceptance for journal publication and take the steps necessary to link that manuscript to the appropriate CRI grant. The manuscript is to be made publicly available in PubMed Central no later than 12 months after the official date of journal publication. This requirement applies to all CRI grants awarded after October 1, 2017.

  CRI is part of the Health Research Alliance (HRA), a national consortium of non-governmental, not-for-profit funders of biomedical research and training. HRA has made arrangements so that PubMed Central will accept deposits of manuscripts and publications resulting from research funded by HRA member organizations. All CRI award recipients are required to create an account with HRA through its Public Access Initiative. Someone from our awards team will be contacting you with information on how to create your HRA account.

- Reprints or preprints of all articles describing research supported by this grant must be submitted by the Principal Investigator. They may accompany progress reports or be sent when available. Advance notice of any publications via email to grants@cancerresearch.org is appreciated. Please be sure to properly acknowledge the Cancer Research Institute in all publications (including abstracts of presentations at scientific or clinical meetings) resulting from research supported by the CRI. In addition, please be sure to acknowledge CRI in any slides you present at meetings or in any other vehicle where you are acknowledging the funds you receive to support your research. The following acknowledgment should be included: **"[Name of Awardee] is supported by a Cancer Research Institute Clinical Innovator Grant (CRI Award#)**." You will receive a digital copy of the Cancer Research Institute's logo which may be inserted into presentations when appropriate.

Invention Policy

- The Cancer Research Institute encourages the rapid development and commercialization of promising new biomedical technologies for the public benefit. In furtherance of CRI's mission of supporting high quality research in basic and tumor immunology, CRI requires that Net Income derived from any Invention be shared with CRI in accordance with this policy.

  "Invention" means any invention, discovery, improvement, modification, work of authorship (excluding journal articles, textbooks or chapters of textbooks) or other work product, whether patentable or not, that is conceived, created, developed, validated or reduced to practice as a result of any research funded in whole or in part by CRI, or which is deemed to be a "work for hire" within the meaning of the U.S. Copyright Act and of which the grantee institution is deemed an author or co-author.

  Unless otherwise agreed, title to an Invention shall reside with the grantee institution pursuant to the grantee institution's intellectual property own ership and licensing policies. The grantee institution agrees to use diligent efforts in obtaining patent and/or copyright protection, as applicable, and in commercializing the Invention. CRI, the grantee institution and the researcher will enter into a revenue sharing agreement in substantially the form of CRI's standard form of revenue sharing agreement, in a timely fashion prior to generation of Net Income from any Invention.

  CRI's share of Net Income from an Invention shall be based on the proportionate amount of direct costs paid by CRI, the grantee institution and other funders, if any, to the research that resulted in the Invention. The first $250,000 of Net Income will not be subject to CRI's share. "Net Income" is defined as income or other consideration resulting from the licensing, assignment or other commercialization of the Invention, less (a) any out-of-pocket expenses of the grantee institution (or the researcher, as the case may be) related to securing intellectual property protection for and commercialization of the Invention, and (b) distributions payable to inventors of the Invention (other than amounts paid as salary or other compensation or stipend support included as direct costs).

  Upon the completion of each award year, and on the first anniversary of the last day of the final award year, the grantee institution, the researcher and, where applicable, the sponsor, shall complete and submit to CRI CRI's standard Intellectual Property Disclosure Form to indicate whether any Invention was developed in the performance of the relevant CRI-funded research. If an Invention was so developed, the grantee institution shall thereafter complete and submit to CRI CRI's standard Intellectual Property Annual Update form to indicate the status of any patents and copyrights and applications therefore, licensing, assignment or other commercialization of the Invention, and Net Income (and related amounts owed to CRI) during the prior year. All information disclosed to CRI marked "Confidential," or, if disclosed orally, described as confidential and promptly confirmed in writing by the grantee institution to be of a confidential nature, will be held in strict confidence and will not be disclosed to any third party without the prior written consent of the grantee institution.

Clinical Trial Registration

- CRI requires all applicable clinical trials to be registered in a clinical trial registry (country specific or international). You must register the clinical trial before the first subject receives the first medical intervention in the trial.

To confirm your acceptance of this award and its terms and conditions, please sign below and return this form to the Cancer Research Institute. Be sure to keep a copy of this form for your records.

The undersigned herewith accepts the Cancer Research Institute Grant and agree to abide by the terms and conditions governing it.

Name of Principal Investigator (please print)

Signature of Principal Investigator

Date:

Name of Officer Authorized to Sign on Institution's Behalf

Title of Authorized Officer

Signature of Authorized Officer

Date: