NExT Application Submission - Quick Guide

Announcement (PLEASE READ BEFORE PROCEEDING)

The NCI is seeking NExT **Applications for Groundbreaking Therapeutic Modalities** with the potential to impact the current landscape and clinical practice in patients afflicted with cancer.

The NCI places an **emphasis on the pursuit of NOVEL TARGETS** and approaches in cancer therapy.

For applicants seeking Development support, a request should be submitted to the Drug Development Consult group (https://next.cancer.gov/experimentalTherapeutics/form.htm).

Applicants seeking a CTEP collaboration will need to contact the NCI NExT Office (NCINExTInfo@mail.nih.gov)

Resources

ProposalCentral (Altum)	https://proposalcentral.com/
ProposalCentral inquiries: Technical support and Troubleshooting Uploads	pcsupport@altum.com
NCI Consultation: Development, Refinement of proposals; scientific inquiries	https://next.cancer.gov/experimentalTherapeutics/form.htm
General Questions and Inquiries	NCINExTInfo@mail.nih.gov
Comprehensive Application Instructions	https://next.cancer.gov/entryToPipeline/default.htm

Application Submission Dates

Application submissions occur in cycles and open (regardless of holidays or weekends) on **January 15th**, **May 15th** and **September 15th** of each calendar year and close one month later on **February 15th**, **June 15th** and **October 15th**, respectively, at 5pm ET. Applications are submitted using ProposalCentral (Altum) at https://proposalcentral.com/.

Scope

Note that a NExT proposal is **NOT a grant application** but rather an application to gain access to scientific capabilities and resources available at the NCI. NExT Program Applications are evaluated for scientific merit, feasibility, novelty, and clinical need. The NExT Program supports various therapies and modalities, including biologics and imaging agents. Special consideration will be given to applications that address unmet needs in oncology, including approaches to exploit "undruggable" targets, orphan malignancies, and pediatric cancers.

General Considerations

NExT Applications comprise of a Concept (5-page maximum), References, and other relevant information that supports the overall request. It is critical that applicants clearly indicate the resources being requested from the NCI in the body of the proposal.

For Resubmissions of previous proposals, please ensure you *carefully* follow the instructions pertinent to application resubmission. For detailed information, please visit or follow the link: Resubmit your NExT Application

The NExT Concept Application should follow PHS 398 font guidelines (i.e., Arial, Helvetica, Palatino Linotype or Georgia typeface, 11 point or larger). All documents should be converted to PDF files, and password protection or other encryption removed before submission.

Required Documents for NExT Applications

1. Downloadable NExT Concept templates can be accessed through the links below and at ProposalCentral:

- NExT Concepts Template for Discovery, Development Investigational Agent Trials
- NExT Concept Template for Multiple Investigational Agent Sponsored Trial

The concept application document should not exceed 5 pages and should outline the scientific nature and rationale of the proposed project according to the follow sections:

I. **Background**: Provide a summary of the field sufficient to allow an appropriate understanding of the scientific and medical context from which the opportunity emerges.

Describe the target, targeted cellular pathways, and molecular mechanism of action, if known. Please be concise and specific; it is not necessary to address cancer incidence.

II. **Hypothesis**: Include a clear statement of the hypothesis(es) to be tested and define the objectives of the proposal. Specifically, address the scientific merit of your proposal by evaluating whether your hypothesis is supported by the field. Provide evidence to validate the target and/or the approach for pharmacological intervention based on in vitro, in vivo, or clinical studies from your research or literature. Provide a summary of the key experiments you have conducted to date; manuscripts and supporting material can be uploaded as an appendix. Include an assessment of safety and therapeutic index. When available, include information on the competitive landscape and comparator efficacy studies.

III. **Research Strategy and Specific Request**: Clearly describe the intended research strategy defining the specific activities requested from the NCI with the proposal; if the research activities necessary to move the concept forward to the clinic are not established or clear, please indicate this. Include specific details as necessary to demonstrate that the project has been well thought out (for example, if requesting assistance in the development of a pharmacodynamic assay, include a description of the analyte to be measured, strategy for biospecimen acquisition, assay platform, etc.). Address the feasibility of the proposed research strategy. For projects involving small molecules or natural products, please make sure to provide drug structural information.

IV. **Justification**: Provide a statement to indicate whether your proposal adequately addresses unmet needs in oncology, including orphan or rare malignancies, pediatric cancers, “incurable” cancers, or cancers not commonly addressed by the pharmaceutical industry. Specify how the proposed compound or approach will advance clinical practice and improve current therapy. For imaging agents, provide an explanation of why the imaging modality represents a particularly innovative or promising approach to the prevention, detection, diagnosis, or treatment of cancer.

V. **Uniqueness**: Include a statement about how the proposed agent or therapy differs from standard therapies in practice or under clinical evaluation. If available, provide comparator efficacy and safety data for your investigational agent (biologic, vaccine, or new molecular entity) or cell therapy approach. Address the novelty of the concept with respect to the target and approach and indicate the likelihood of the concept advancing into the clinic without the assistance of the NExT Program.

2. For NExT Application for Multiple Agents for NCI-Sponsored Clinical Development in the Experimental Therapeutics Clinical Trials Network (ETCTN), please use the link below

NExT Concept Template for Multiple Investigational Agent Sponsored Trial

3. NExT Application Required Documents

Attachments for ProposalCentral (PC) uploads. These follow the order of attachments in the PC application (Section 8). Required attachments are indicated where noted in the list below. Figure 1, below, shows the view from PC as it aligns to the list presented here.

a. **NExT Concept (*required*):** 5-page (max) concept which includes the sections mentioned on the previous page. This will be the first attachment that is uploaded as part of the application submission in ProposalCentral. For Multiple Investigational Agent Sponsored Trials (8-page max).

b. **References (*required*):** Following the NExT Concept, a separate document can be uploaded for all literature references from the concept. Proper scientific citations should be used (e.g. J. Med.Chem

c. **Preliminary Data (*required, 10 pages max*):** Include any supporting data (e.g., figures, tables, and descriptions) that directly supports the content provided in the NExT Concept. **For small molecule proposals, please provide the structure of the proposed lead or candidate.** Please DO NOT use this section as additional page space to continue elaborating on the Background, Hypothesis, Research Strategy, Justification or Uniqueness sections. This section is solely intended to provide data that directly supports the narrative outlined in the NExT Concept.

d. **Resubmission Summary and original concept (*REQUIRED FOR RESUBMISSIONS*):** For NExT Application resubmissions of previous NExT Applications, please include the 2-page resubmission summary and original 5-page NExT concept.

e. **Principal Investigator Biosketch (required):** The principal investigator biosketch should follow the NIH standard format.

f. **Intellectual Property (IP) Information (*required, 2 page max*):** The applicant should include a list of any patents issued or pending with respect to either the agent or to any non-commercially available technology/material required for the development of the agent. If an application requires the use of non-commercially available technology/equipment that is patented by a third party, the applicant must provide documentation that the patent holder does not object to the applicant's use with the proposed project. Provide a statement if there is no applicable IP information.

g. **Current and Pending Support (*required*):** Please provide a list of current and pending funding sources. For applicants in academia, this would include current grants from both government and non-government sources, and any research resources provided directly from their institution. Individuals working directly for the government should provide an annual budget for their laboratory and any additional outside funding sources.

h. **Clinical Letter of Commitment (*optional*):** All investigators requesting production of clinical-grade material and/or IND-directed toxicology studies **must** provide a letter of commitment from their institute. This letter is intended to ensure the reviewers and the NCI that the products and data produced by the NExT Program have a clinical outlet, and as such, the letter should indicate that the institution is committed to the filing of an IND and conduct of a clinical trial.

i. **NCI BRB Generic Questionnaire for BioPharmaceutical Production Candidates (*optional, except for biologics manufacturing proposals*):** If submitting a project involving the discovery or development of biologics, please complete the appropriate NCI Biological Resources Branch (BRB) Questionnaire and include it in the appendices of the application.

j. **Investigator's Brochure (*CTEP*):** Required for CTEP applications seeking clinical trial support. Optional for Development applications.

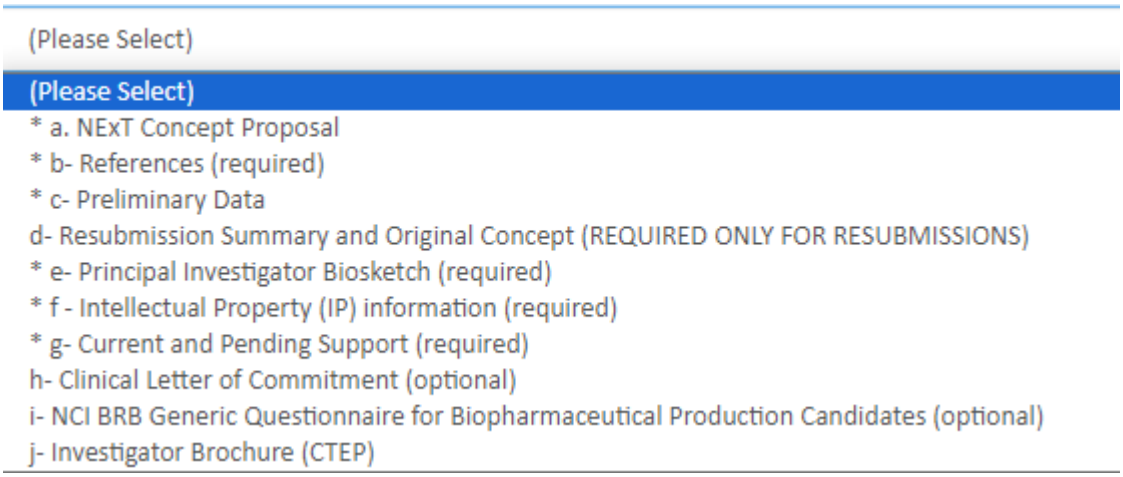

Figure 1: dropdown in PC Section 8 showing the attachment options and order corresponding to the list above. **All asterisks indicate required documents.**

For detailed instructions on preparing and submitting your NExT Application, please refer to the instructions available on the next.cancer.gov website or by clicking the link provided here (NExT Application Submission – Detailed Instructions)