

Questions and Answers for RFA-CA-19-009, U.S.-China Program for Biomedical Collaborative Research (R01 Clinical Trial Optional)

NIH published this RFA in a [January 2, 2019, Guide notice](#).

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About the Program

What is the purpose of the U.S.-China Program for Biomedical Research Cooperation?

The purpose of the U.S.-China Program for Biomedical Collaborative Research is to stimulate collaborative basic, translational, and clinical research between United States (U.S.)-based researchers and Chinese researchers in the areas of cancer, environmental health, heart disease, blood disorders, diseases of the eye and visual system, mental health, and neurological disorders. Partnering U.S. and Chinese investigators must work jointly to submit identical applications to NIH and National Natural Science Foundation of China (NSFC), respectively. U.S. investigators must respond to the announcement from NIH, including the Chinese application as an attachment, and Chinese investigators must respond to a separate funding announcement from NSFC, including the NIH application as an attachment.

What is NSFC?

NSFC is the National Natural Science Foundation of China. For more information, visit the [NSFC website](#).

Will there be another cycle for this Request for Applications (RFA)?

At this time, it is not clear if this RFA will be reissued in the future.

Eligibility

What are NSFC's eligibility requirements for Chinese collaborators?

Chinese collaborators must be current or former NSFC grantees.

Potential collaborators and scientists in Special Administrative Regions of China (e.g., Hong Kong) should contact NSFC to discuss their eligibility requirements.

For more details on eligibility requirements for Chinese collaborators, go to the [NSFC Funding Opportunity Announcement](#) (in Chinese).

What are NIH's eligibility requirements for U.S. applicants?

Read the [January 2, 2019, Guide notice](#) and note the following:

- Chinese collaborators must be current or former NSFC grantees.
- To be considered for funding, both the U.S. and Chinese applications must be determined to be eligible and responsive by their respective organizations.

May applicants outside the U.S. apply for funding from NIH?

No. Foreign institutions and non-U.S. components of U.S. organizations may not apply for funding.

Applications must list at least one investigator from a U.S. institution as the Program Director/Principal Investigator and name the Chinese investigator as a collaborating partner.

May federal institutions apply for funding?

Yes. Note that federal institutions must ensure that their authorizing legislation allows them to receive NIH grants and comply with the terms and conditions of an NIH award.

Contact your agency to find out if it is eligible.

May NIH intramural investigators apply for funding?

Yes. Intramural investigators from NCI, NIEHS, NEI and NINDS are eligible. Investigators from other institutes are not eligible. Eligible intramural investigators should consult their respective IC contacts concerning financial support for proposed projects.

For more information, contact:

1. For NCI PIs, contact [Paul Pearlman](#).
2. For NIEHS PIs, contact [Andrea Horvath Marques](#)
3. For NEI PIs, contact [Lisa Neuhold](#).
4. For NINDS PIs, contact [Claudia Scala Moy](#).

Is the submission deadline for U.S. extramural investigators, NIH intramural investigators, and Chinese investigators the same?

No, the deadline for U.S. extramural and intramural investigators to NIH is February 21, 2019 at 17:00 (local time). The deadline for Chinese investigators to NSFC is February 21, 2019 at 16:00 (Beijing time).

Does a U.S. applicant have to hold an active NIH grant?

No.

Research Areas

What research areas does this initiative support?

This initiative supports research areas outlined in the [Funding Opportunity Description](#) in the [January 2, 2019, Guide notice](#). It does **not** support the following research activities:

- Clinical trials (because of NSFC's policy restrictions).
- Research involving select agents.

Can U.S. investigators apply with a pathogen or research area that is not listed in the announcement?

Possibly, depending on the research focus (as indicated for each participating NIH institute) and its relevance to the intent of this initiative.

Before submitting their applications, U.S. investigators should discuss research plans with a Scientific/Research Contact listed in the [January 2, 2019, Guide notice](#).

Note, however, that certain restrictions to permissible scientific activities are defined in the announcement.

How to Apply

How does a U.S. investigator and a Chinese collaborator create an application?

A U.S. investigator and Chinese collaborator work together to create a joint application that they submit to their respective agencies as follows:

- The application should be jointly prepared through consultations between the collaborators. It should specify what role each collaborator will have and where the proposed research components will be executed, along with all the other elements required in the FOA.
- Once completed to the satisfaction of both collaborators, the U.S. investigator submits the application to NIH and shares a copy in English with their Chinese collaborator.
- The Chinese collaborator submits a copy of the U.S. application in English to the NSFC along with all additional components required by the NSFC in Chinese. Specifically:
 - The NSFC application requires Chinese collaborator to submit the NIH application in English *and* a research proposal (not only the abstract) translated into Chinese to ensure both research proposals are identical. The budget, biosketch, and other administrative sections of the English application from the U.S. PI do not need to be translated into Chinese.

- The title of the Chinese application should be identical to the title of the English application.
- Applicants should clearly describe in detail how the U.S. and Chinese collaborative efforts will be integrated to accomplish the research proposed in their applications. The English application materials are the basis for scientific merit review by both sides.
- It is expected that the Chinese collaborators and their collaborating U.S. PIs will be in close contact so that a copy of the application submitted to NIH will also be available to the Chinese collaborators. When submitted to the NSFC, this application will be kept confidential during the NSFC review process.

The Chinese collaborator should check the [NSFC Funding Opportunity Announcement](#) (in Chinese) for additional information.

What is a multi-PD/PI application?

This RFA allows multiple PIs, which means more than one principal investigator at one or more institutions. Each is a full-fledged PI who has responsibilities appropriate to that role. There should be only one U.S. contact PI. Include a leadership plan for a multi-PI application.

May I submit a multiple PD/PI application?

Yes. You may submit a multi PD/PI application, but for this RFA all PDs/Pis should be U.S. investigators and the Chinese investigator should be named as a collaborating partner. Unless you have multiple PDs/Pis at your U.S. site, a multi PD/PI application is not necessary.

Should a U.S. applicant include the Chinese collaborator's biosketch?

Though not a requirement, NIH strongly encourages you to provide a biographical sketch for all Senior/Key Personnel.

Which budget format should be used for this RFA, modular or detailed (R&R)?

Applicants in response to this FOA must use the R&R (detailed) budget. If you receive a warning that the wrong budget format is being used, you may ignore it because warnings will not stop the validations process.

Should the Specific Aims and Research Strategy sections describe the details for both U.S. and Chinese collaborators' work?

Yes. Applicants should describe the Specific Aims in a one-page attachment, concisely stating the goals and expected outcomes, including the potential impact on the field. In the 12 pages of the Research Strategy, applicants should clearly describe how they plan to achieve the Specific Aims of the project and the organizational structures, roles, and responsibilities of the U.S. PD(s)/PI(s) and NSFC collaborative partners in accomplishing the proposed research.

The RFA instructs applicants to include a description of the collaborative research, detailing the integration of the U.S. and Chinese collaborative efforts.

This same application, including *details* of the work done by the U.S. PD/PI and China collaborator, will also be reviewed confidentially during the NSFC review process.

May I submit my application late?

NIH will not consider accepting late applications for this RFA.

Do early stage or new investigators receive any special consideration?

No. Early stage and new investigators will not receive any special consideration.

How do I indicate which institute my application should be assigned to?

In the cover letter, applicants should clearly indicate the area of science proposed in the application and the preferred NIH institute.

Can NIH help U.S. applicants obtain approval from the Chinese government to export biospecimens out of China?

No. U.S. applicants should work closely with their Chinese collaborating investigators, who are responsible for obtaining the necessary approvals.

If the proposed research requires exporting biospecimens from China, U.S. applicants must include the following information in their applications:

- Type of biospecimens to be exported.
- Evidence that the applicant has already applied for the required Chinese government approval to export these materials.
- Indication of whether the work can be completed if the Chinese government does not grant this approval.

In addition, a Material Transfer Agreement (MTA) may be needed for exchange of materials between two institutions. Contact the authorized organizational representative (AOR) at both organizations for institutional requirements (e.g., intellectual property issues). Also work with the AORs to address federal regulations for each country (e.g., customs.)

Can an applicant submit an application to this program and also as an independent R01 (with a five-year budget)?

No. You cannot submit a closely related application for an independent R01 before a funding decision is made for this application. As explained in the [May 15, 2009, Guide notice](#), NIH will not accept similar grant applications with essentially the same research focus from the same applicant organization.

Does the collaborator in China need an NIH Commons user name?

No.

Must the PI in the U.S. have an active NIH R01 and should it remain active until the end of the proposed study?

No. You do not need to have an active - NIH R01 to be eligible to submit an application in response to the RFA.

May I submit a Letter of Support co-written and electronically cosigned by the PD(s)/PI(s) of the U.S. institution and the Chinese collaborating partner and cosigned by the authorizing institutional officials?

Yes. Submit the Letter of Support to grants.gov as a PDF. A scanned copy of hard signatures is acceptable.

Is there a limit to the amount of travel funds that can be requested by the U.S. applicant?

There is no limit to the amount of travel funds that the U.S. applicant can request; however, the U.S. applicant will need to justify the requested budget. Reviewers will also consider whether the budget and the requested travel funds are justified and reasonable.

Do U.S. investigators need to include their Chinese collaborators' budgets in their applications?

No, it is not required; however, NIH encourages U.S. investigators to include this information, as well as a budget for any activities that they plan to undertake in China, as separate, clearly marked attachments to their NIH applications (in English). Use the Other Attachments option on the Research and Related Other Project Information form. *Do not* use NIH application budget forms for the Chinese budget.

Must I include a data sharing plan?

All applications, regardless of the amount of direct costs requested for any one year, should include a data sharing plan. Applications should follow the [NIH Data Sharing Policy and Implementation Guidance](#).

Does the Chinese collaborator's NSFC application need to be submitted as part of the NIH application?

Yes. The NSFC application is to be submitted as an attachment (in English) to the proposal.

Do U.S. investigators need to share confidential or proprietary information with their Chinese collaborators?

Only if they include this information in their applications. PIs concerned about confidentiality or proprietary information should take the sharing requirement into account when deciding what information to include.

Can NIH staff send confidential or proprietary application information to a Chinese collaborator on behalf of an applicant?

No. Only applicants can send this information to their collaborators.

What is the maximum budget that U.S. applicants can request?

U.S. applicants can request up to \$150,000 a year in direct costs for up to five years. The partner application to the NSFC will cover the budget for activities in China.

How much funding can Chinese collaborators request from NSFC?

Chinese collaborators can ask for up to 3 million renminbi to support the five years of the project. For more information, go to the [NSFC Funding Opportunity Announcement](#) (in Chinese). Any specific questions regarding funding for the Chinese collaborators should be addressed by NSFC.

Are references included in the 12-page limit for the research strategy?

No.

Must U.S. applicants show evidence of collaboration history with their Chinese collaborators?

No.

Can a U.S. applicant submit more than one application on different projects, each with a different Chinese collaborator?

Yes, as long as the applications are scientifically distinct. Note that NIH will not accept any application that is essentially the same as one already reviewed or pending initial peer review.

Review

Are applications reviewed the same way as other R01s, including the requirement for preliminary data?

Applications in response to this RFA will be reviewed based on the review criteria in the RFA, not like a standard R01. As stated in the RFA, "Unlike a standard R01 application, preliminary

data are not required under this FOA; however, supporting evidence for past productivity, proposed approach, and techniques should be included."

How important is the NSFC-funded portion of the project—namely, do you wait to see if it is funded before reviewing the American component?

The NSFC-funded portion of the award is extremely important. The application is incomplete without the component of the work that will be supported by NSFC and would not be peer reviewed without it. U.S. applications and NSFC (Chinese) applications will be received and reviewed independently by NIH and NSFC respectively before funding decisions are made.

Are these R01s percentiled?

No. These R01s are not percentiled because the applications are received and reviewed in response to the RFA. Applications in response to an RFA are usually funded based on the priority score and programmatic importance.

How will funding decisions be made by the NIH and NSFC?

Funding decisions for applications submitted to NIH will be made by NIH based on merit, with consideration of the research priorities of the U.S.-China program and in consultation with the NIH-NSFC Executive Secretariat. In the parallel processes conducted by NIH and NSFC, both the U.S. and Chinese applications must be determined to be eligible and responsive to be considered for funding under the program.

Do U.S. institutions pay for facilities and administrative costs for Chinese collaborators?

U.S. institutions do not pay for facilities and administrative costs for their Chinese collaborators; however, they can include items needed at any foreign site (whether in China or elsewhere) as direct costs in their budgets.

Chinese collaborators receive support directly from NSFC.

Will applicants receive feedback from NIH?

Yes, the U.S. applicants will receive feedback in the form of summary statements after peer review of their applications.

How will NSFC review applications?

NSFC will review applications from Chinese collaborators using review criteria that match NIH's.

Will reviewers consider the Chinese collaborator's scientific background when evaluating a U.S. investigator's application?

Yes. Reviewers will evaluate all investigators for appropriate scientific background to conduct the proposed research.

How does NIH review applications?

Applications will be evaluated for scientific and technical merit in study sections at the Center for Scientific Review. Applicants can see their review assignments in the [eRA Commons](#) after they apply.

What if NIH and NSFC do not reach a consensus regarding an application?

NIH will review all extramural applications through the Center for Scientific Review while NSFC will review applications from Chinese investigators using their systems. NIH will rank each application as high, middle/intermediate, or low, based on the merits of the applications, and NSFC will do the same. NIH and NSFC will discuss the applications, and applications that are ranked as highly meritorious by both sides will be recommended for funding (depending on the number of such applications and the funds available). Applications that are ranked low by both sides will not be recommended for funding. Applications that receive a high ranking from one side and a low ranking by the other will be discussed; a consensus will be reached over whether the application will be recommended to receive funding. There has never been a situation in which a consensus was not reached following discussion.

Other

My collaborator in China will be working with human samples or vertebrate animals. Should I submit a complete human subjects (HS) or vertebrate animal section in the application even though I will not be doing those studies in the U.S.?

Yes, you must complete the human subjects section in the application if you or your collaborator in China will be doing research involving human subjects. Similarly, if you or your Chinese collaborator is planning to work on animals, you should complete the Vertebrate Animal section in the application.

Applicants and collaborating partners are expected to adhere to NIH regulations for the conduct of research involving human subjects and vertebrate animals.

Whom should I contact if I have a question regarding this announcement?

Contact the appropriate Scientific/Research Contact listed in the [January 2, 2019, Guide notice](#).