

RFA-HD-20-003 - Centers for Collaborative Research in Fragile X and FMR1-Associated Conditions (P50 Clinical Trial Optional): Frequently Asked Questions (FAQs) and Answers

The following FAQs and answers are related to [RFA-HD-20-003](#).

FAQ	Answer
Will the submission deadline be extended due to COVID-19?	<p>On March 26, 2020, NIH published an updated late application policy (NOT-OD-20-091). With this Notice, NIH announced that all grant applications submitted late for due dates between March 9, 2020, and May 1, 2020, will be accepted through May 1, 2020. This includes all applications submitted in response to RFA-HD-20-003: Centers for Collaborative Research in Fragile X and FMR1-Associated Conditions (P50 Clinical Trial Optional).</p> <p>Please note that this supersedes the previously published late application policy. Applications will not be accepted after May 1. Additional allowances for institutional closures cannot be applied on top of the extension through May 1.</p> <p>We recognize that this is a rapidly evolving situation. The NIH Office of Extramural Research (OER) offers updated information regarding COVID-19 for NIH applicants and recipients of NIH funding at: https://grants.nih.gov/grants/natural_disasters/corona-virus.htm. Please refer to this OER page frequently for any updates/changes.</p>
Are Centers required to address more than one FMR1-associated condition?	No. Such applications are welcome, but this is not a requirement.
Are multi-institution proposals allowed?	Yes. Such collaborations are encouraged, particularly if they provide the expertise needed to meet the requirements of the request for applications (RFA).

FAQ	Answer
Is it correct to say that studies of brain/behavioral outcomes cannot be comprised only of mouse studies?	Correct. Studies of brain/behavioral outcomes can include mouse or other animal studies, but must also include human subjects or human materials.
The FMR1 strategic plan discusses the importance of understanding sex differences, but I don't see specific language about this in the RFA?	<p>Yes, this is certainly an area of interest. We intended this to be captured under the following priority area:</p> <p>Characterize phenotypes of FMR1-associated conditions and risk factors for disease severity across developmental stages and diverse populations</p>
Are human induced pluripotent stem cells (hiPSCs) allowed? Do they meet the requirement for human studies?	Yes, they are allowed, and yes, they meet the requirement for studies of human materials.
Are there requirements for which specific hiPSC lines can be used?	There is no requirement for use of specific existing cell lines. Any hiPSCs used should meet the RFA requirements for rigor of design, conduct, analysis and results reporting, as well as NIH-wide requirements for rigor and reproducibility of research.
Are we required to include more than one species for mechanistic projects?	Projects addressing the priority area of developing and validating biomarkers must include both animal studies and studies of human subjects or human materials. For projects addressing other priority areas, inclusion of multiple species is encouraged but not required.
I am an appointed study section member with continuous submission privileges. Does that apply to this RFA?	No. Continuous submission only applies to R01s, R21s, and R34s submitted to Funding Opportunity Announcements (FOAs) using standard due dates. This RFA does not use any of these mechanisms and does not use standard due dates: therefore, applications are not eligible for continuous submission.
I recently submitted an R01 on Fragile X syndrome (FXS). Can I include any part of that project in a Center application?	No. NIH policy states that you cannot have duplicate or highly overlapping applications under review at the same time. (An application is considered "under review" until the summary statement is issued.)

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Are allowable costs for the administrative core limited to those listed in the RFA?	No. But if you are considering other categories of costs, you are strongly encouraged to contact a member of the NIH program staff to determine whether they are consistent with the goals of this funding opportunity.
Are cores other than the administrative core allowed?	No. This FOA only allows for one administrative core and 2 to 3 research projects – no other cores are allowed.
I see that an External Advisory Committee is required. Would an internal advisory board also be allowed?	Yes. This would be allowed, although it is not required.
Why is animal model data needed for biomarker development if we already have validated results for a biomarker in humans?	The type of biomarker development and validation we seek to support through this funding opportunity is specifically for biomarkers that are conserved across humans and animal models of FMR1-associated conditions and have the potential to accelerate bidirectional translation (translation from animal models to humans and translation from humans back to animal models). Therefore, applications proposing to address this priority area must include both animal studies and human validation research.
Are for-profit organizations eligible to apply? Could the for-profit organization be a start-up company?	<p>Yes, for-profit organizations are eligible to apply, and could be start-ups.</p> <p>Please note that reviewers will use the same criteria, including some relevant to investigators and environment, to score all applications regardless of whether they come from a start-up, non-profit, university, etc.</p> <p>As outlined in the FOA, all applications must include a Resource Sharing Plan that is appropriate and consistent with the goals of the Fragile X Centers program. Plans that rely on proprietary methods or that require payment for sharing data are not consistent with the goals of the program and will not be considered as responsive.</p>

FAQ	Answer
<p>The “Research & Related Other Project Information (Overall)” section of the FOA requests that applicants describe how the Center’s research effort will be prioritized within the participating institution(s). Does this refer to management of the proposed research activities within the Center? Or is it asking about the priority of the proposed Center in relation to other sponsored activities at the institution?</p>	<p>The description should address the priority of the proposed Center in relation to other research activities within the department(s)/institution(s).</p>
<p>Of the 3 components (basic, clinical, translational) mentioned in the FOA, is there a minimum number required to qualify as a specialized center (e.g., 2 out of 3), or are all 3 components necessary?</p> <p>Or, put another way: Is an application required to include basic, translational, and clinical research components?</p>	<p>Centers are not defined by components, but rather by research projects. Each research project must be responsive to the requirements of the RFA by including least two distinct levels of analysis within one or more species.</p>
<p>I have an offer of modest financial support from my institution to support some of the activities of the proposed center. Is this allowable?</p>	<p>Yes. There is no prohibition against additional institutional support.</p>
<p>It is clear that the center can have multiple PIs. Can individual projects also have multiple PIs?</p>	<p>The “multiple PI/PD” designation applies only to the overall award. Individual projects may have co-leads, but leadership issues for individual projects would be managed/adjudicated by the center’s administrative core, not directly by NIH.</p>
<p>Are there budget limits for specific components (e.g. administrative core, individual projects)? Or just for the overall center?</p>	<p>There are no budget limits for specific components, only a limit on the overall budget for the center.</p>
<p>Can a component of the application be based at a foreign institution?</p>	<p>Yes. Although this funding opportunity will not accept submissions from foreign institutions, foreign components are allowed within applications submitted by U.S.-based institutions. Keep in mind that all aspects of the proposal, including any foreign components, must comply with the RFA requirements for data sharing/resource sharing.</p>

FAQ	Answer
Is preliminary data required for each project?	No. We encourage applicants to include preliminary data if they are available, but it is not required.
In order to qualify as a “circuit/network” measure, do 2 measures need to be taken in the same subject or animal simultaneously? Or could we just look at 2 regions in the same project (e.g., one region in half of our animals and another region in another half of our animals)?	In order to be considered a circuit or network measure, data would have to be collected from (at least) 2 nodes within the network simultaneously, in the same person or animal. Doing recordings from 1 region in some animals and another region in other animals would not meet this requirement.
Do brain circuit/network studies have to be conducted in humans?	No. They can be animal studies, as long as some other aspect of the project involves human subjects or human materials.
We are proposing a Center with a multiple PI (MPI) structure. Does the requirement for a minimum combined total commitment of 1.8 person-months (15% effort) apply to each MPI individually, or can the combined MPI effort equal 15%?	In the case of MPI proposals, the 15% minimum effort requirement applies to each person who is a named PI.
Are we allowed just one Specific Aims page for the entire application? Or can we have a separate Aims page for each section (i.e., overall, administrative core, research projects)?	You may have a separate aims page for each section.