NJ Autism Center of Excellence (NJ ACE)
Frequently Asked Questions (FAQs)

I. Clinical and Translational Research and Basic Science Research Applications

Note: FAQs #1, 5 and 6 regard re-applications and clinical issues and only apply to Clinical and Translational Research applications

1. Rolling over applications and addressing critiques

Note: This FAQ refers to those applicants who applied to the previous RFA for the Clinical Research or Translational Research Pilot Project grants and were not funded.

Q. I have rolled over my previously submitted application in SAGE and see that we have to reenter everything. Can we revise our original submission as we wish, or do we need to re-submit the same document exactly as before and separately address the critiques?

A. You need to re-enter the text, revising your original application as you wish. It is considered a new application. You'll address the reviewers' critiques in the "Response to Reviewer's Critiques" box.

2. Percent effort of staff:

Q: Are there any guidelines in terms of % effort for the various positions such as PI, research associate, clinician, etc.?

A: The Grant Guidelines do not include specific guidance regarding the percent effort of the PI and other staff members to allow flexibility in the organization of the team. The final proposal will depend on the specific objectives of the program and the capability of the staff members. The specifics of the budget can be revised during the project period based on the evolving needs.

Q. Can I have a co-Principal Investigator?

A. The Principal Investigator is responsible for the execution of the project. Furthermore, the application is not structured to accommodate a co-Principal investigator, but a co-Principal Investigator can be listed in the key personnel and can be a subcontractor. The collaborator can be funded through a subcontract.

3. IACC Objectives

Q: What does the Council expect? What are their priorities/expectations?

A: The Council expects to fund strong pilot projects that address some of the outstanding questions in the field of autism and provide data to inform clinical practice. The objective is to improve the lives of patients with ASD. Research projects will need to 1) address one of the subset of IACC objectives listed in the RFA and 2) clinical or translational research must meet the NIH definitions of clinical research as described in the RFA.

The subset of IACC objectives listed in the RFA were selected from the Interagency Autism Coordinating Committee (IACC) Strategic Plan and are those objectives with the potential to improve the physical and/or behavioral health and well-being of individuals with ASDs. The Council is particularly interested in projects with potential direct clinical impact.

Q: IACC objectives are so wide open - should we address more than one objective? Is it too narrow to pick just one objective?

A: The national priorities described in the Interagency Autism Coordinating Committee (IACC) Strategic Plan, and more specifically, the subset of IACC objectives applicable to this grant (listed in the RFA), represent the consensus of the experts in the field of ASD. Very few of these objectives can be met in a year. Successful projects will need to clearly articulate their research approach, and therefore are unlikely to be able to address more than one objective. While a research team with exceptional strengths in many areas and access to large numbers of patients could possibly propose a couple of small studies related to several objectives, it is not known whether the Council would ultimately choose to fund such a project over a focused project that provides strong conclusions related one IACC objective.

Q: Haven't these objectives already been done?

A: The IACC objectives are revised regularly, to reflect the evolving state of the science and public health needs. Most if not all of the IACC short- and long-term objectives will require data from more than one research project. The regular evaluations of the IACC strategic plan are based on an analysis of the existing grants portfolios.

NDAR and the Resource Sharing Plan

Q: What are the advantages of using NDAR?

A: Pilot project grantees are strongly encouraged to use the National Database for Autism Research (NDAR) if compatible with the design of the projects. The New Jersey data will

therefore be made available to autism researchers from around the United States, highlighting the New Jersey effort. Furthermore, participation in NDAR demonstrates that the funded projects are capable of meeting the National Institutes of Health (NIH) requirements and will help them develop stronger proposals for submission to the NIH and biomedical research foundations.

Q. I am writing to clarify what is being requested in the Resource Sharing Plan in the grant applications. It is my understanding that we do not need to incorporate NDAR measures into our study if they are not compatible with the design of the study. Do we need to complete the Resource Sharing Plan section if we are not collecting NDAR measures? If yes, what should be included in this section?

A. You are correct in that the grants do not require the use of NDAR to share data. You can respond to the section by saying that your research design is not compatible with the collection of the data necessary for inclusion in NDAR. You would still need to describe how you will share data and other resources with other researchers.

4. Staff

Q. Can the PI on one grant application be included on other grant applications (not as a PI on the other applications)?

A. Yes. However, no person can provide more than 100% effort across his/her projects.

Q. In section "M. Experience:" How is "qualifications" being defined? Is it referring to certification or lic. etc.? If not how is it different than section "L. Key Personnel" "expertise"?

A. Experience refers to qualifications (credentials, experience) and time commitments as related to the proposed project. Key Personnel is asking for roles, responsibilities and expertise within the proposed project.

Q. *We plan to use a non-profit operated by family members of one our project staff as a training site. The staff person's time is in-kind on the grant, the trainees are not being charged for the training and the non-profit is receiving no compensation for providing the training. We will secure IRB approval for the entire project. Is our plan acceptable?*

A. Because this was the first request of its kind received by the Council staff, we found it necessary to discuss financial and ethical considerations with the applicant in evaluating the request. We concluded the plan was acceptable as discussed and notified the applicant that the external review panel will comment if they identify a problem with the plan as written in the grant application.

5. Clinical research vs. clinical services

Q. Is this grant cycle meant for isolated research apart from the clinical work we do?

A. Yes, the grant program does not fund services for patients per se. The subjects involved in the research project will receive clinical care within the parameters set by the study. The Council expects to fund strong projects that address some of the outstanding questions in the field of autism and provide data to inform clinical practice. The objective is to improve the lives of patients with ASD.

Q. Our assumption is that the RFA is not looking for a service program, but clinical or translational research. Our project will involve diagnostic testing and treatment interventions, but not necessarily asking for funding for all of these. What can we utilize grant funds for?

A. The grant will only cover research expenses related to the specific research protocol. The use of funds from other sources is allowed and should be detailed in the application. The other sources of funds must be within the parameters set by the funding source, be fully disclosed and not duplicative.

Q. We are going through the requirements for the pilot clinical application and we do not see a specific place for information that would be in a clinical protocol such as inclusion/exclusion criteria etc. We are assuming that this information is to be placed in the "experimental design section" and that there is not a specific "clinical protocol" section. Is this correct?

A. Yes, you are correct.

6. Research subjects

Q. When research subjects are recruited from a clinical center, do the clinical patients diagnosed with autism all need to be enrolled in the NDAR protocol with the minimal data requirements described in the grant?

A. Information about subjects involved in the research project can be shared via NDAR. Information about patients, who do not participate in the research project, should not be shared, even if they are treated at the same clinic.

Q. Can we use data collected for routine clinical care for which we are not asking for funding, for example for a control group?

A. Yes, it is acceptable to pay for part of the research project via other funds. A Principal Investigator can use data collected through routine medical care IF the patients have consented

and the medical care is part of the established protocol. This should be made clear in the application.

Q. Do investigators need to have Collaborative Institutional Training Initiative (CITI) training or is the NIH webinar training for Protection of Human Subjects sufficient?

A. The NIH webinar training is sufficient.

Here is an excerpt from the State's IRB policy:

All personnel engaged in Human Subjects research must have successfully completed an industry-standard program of Human Subjects Research Ethics Training within the past three (3) years and maintain such certification in current good standing for the duration of the research project. NJDHSS will accept certification of completion of the CITI or NIH/CDC courses as satisfying this requirement, and may, at its discretion accept certification from other recognized programs.

Q. For the "targeted/planned recruiting table in section J. Is the NIH template acceptable or is there additional information needed?

A. Yes, the NIH template is acceptable.

7. Responsibility for data analysis

Q. Is the NJACE Coordinating Center going to provide all the statistical and data analysis support? i.e. do applicants need to budget for it?

A. Grantees should expect to do their own data analysis. The Coordinating Center may help with sharing expertise across pilot projects. The Coordinating Center can provide statistical consulting.

8. Environment, Resources and Environment, Facilities

Q. Section "Environment" seems to be at least in part redundant to "Resources and Environment", "Facilities". Is the same information to be put in both places or are they asking for something different?

A. Environment is asking for a description of the overall environment beyond a list of facilities and equipment. Once you answer question "Environment" you'll be able to use some of the information to complete Resources and Environment and Facilities.

9. Literature

Q. I am seeking clarification in regarding to the literature citation portion of the grant application. I just want to make sure that the all of the literature used to support the project proposal will be cited under letter I (Literature) and not elsewhere in the application (specifically under the research design). And as such, in-text citations will suffice for the remainder of the document.

A. Yes, that is correct. The literature is the reference section.

10. Budget

In general, there are no specific budgetary caps or restrictions, except that all requests must be necessary and justified for the grant. The SAGE application contains links to relevant Department of Health (DOH) policies.

Q. Is there a cap on Principal Investigator's (PI) Salary?

A. There is no cap on PI salary. Percent effort must be justified.

Q. Is there a cap on Travel each year?

A. Travel also must be justified. Travel to training sessions is the responsibility of the NJACE Coordinating Center.

Q. Are there restrictions on supplies/equipment such as computers, printers, etc.?

A. Supplies and equipment can be included only if they are necessary for the project. Applicants proposing to purchase equipment which will be used across multiple grants/programs should pro-rate the costs of the equipment across programs and show the calculation of this pro-ration in their justification. If an irregularity is found where equipment is being used by other programs without reimbursement, funding will be reduced accordingly.

Q. Are there restrictions on staff (i.e., admin staff, students, and postdocs)?

A. Administrative staff that will support the project can be included in the application. Students or postdocs would similarly need to be specifically working on the project. Applicants proposing to utilize the same principal investigator or contractual staff across multiple grants/programs should assure that the combined funding for each position does not exceed 100% FTE. If such an irregularity is found, funding will be reduced accordingly.

Note: Upon acceptance of a grant award, the applicant's organization assumes legal and financial responsibility for awarded funds and the conduct of supported activities. It is the responsibility of the applicant's institution and principal investigator to assure the accuracy and validity of all fiscal, scientific, and administrative information pertaining to the awarded grant. Failure to comply with these terms may result in grant termination.

Q. We plan for a two year pilot study. Can we divide the $400,000 unevenly between the two years with justification?

A. The budget can be no more than $200,000/year so you would have to budget evenly. If you don't use the $200,000 the first year it will roll over to the second year assuming Council approves continuation funding based on your progress report for the first year. If the $400,000 is not spent after year 2 you can request a no cost extension.

Q. For a Pilot Project for two years, it is up to $200K per year?

A. Yes, the Pilot Project grants are up to $200,000/yr., total of up to $400,000 for two year grants.

Q. Is there a limitation for budgeting purchase of a device for the project?

A. Supplies and equipment can be included only if they are necessary for the project. Applicants proposing to purchase equipment which will be used across multiple grants/programs should pro-rate the costs of the equipment across programs and show the calculation of this pro-ration in their justification. If an irregularity is found where equipment is being used by other programs without reimbursement, funding will be reduced accordingly.

Q. I did not see a section for budget justification in the RFA. Are the two sections, "Key Personnel" and "Experience" taking the place of a budget justification? If not where do I put the justification?

A. The justification for the first year budget is part of Schedules A-C in SAGE. As you complete each schedule you will need to complete the corresponding justification page(s). You don't need a justification for the year two budget if a general description of how funding will be used in year two is included in the program plan (included in one of the narrative questions).

11. Institutional Support

Q. Where is the statement about providing a letter from an institutional official indicating that there was support and space for the proposed work, such as a Department Chair, or a Dean of research?

A. The statement is included as a note at the end of Environment:
Note: Please attach a letter of support from a president, dean or other authority, as evidence of institutional support, labeled and attached as "Miscellaneous Attachments" in SAGE.

12. Scoring the applications:

Q. How are the criteria for independent scientific review of the applications ranked/weighted? The criteria are specified in the RFA, but no weighting is mentioned.

A. The reviewers will assign to each application an overall impact score reflecting the potential impact on the field of autism and ultimately on New Jersey ASD patients and their families. The impact score will be based on NIH criteria. Scores range from 1 to 9 with 1 being the highest impact score.

The reviewers will consider the following core criteria in determining the overall impact score: significance, innovation, experimental design and capability, environment and key personnel. The overall potential impact of an application depends on both the importance and the feasibility of the proposed project. The significance and innovation core criteria will inform the importance of the project, whereas the other core criteria inform its feasibility.

Reviewers will also take into account the budget, yearly project objectives, the protection of human subjects, inclusion of women, children and minorities, the recruitment and community engagement plans and the resource sharing plan.

Each of the core criteria is scored and used to help the reviewers determine the overall impact score, but the criterion scores are not to be weighted explicitly. It is up to each reviewer to determine an overall score that best describes the likely overall impact that each application will have on the field of autism and ultimately on New Jersey ASD patients and their families.

The application does not need to be strong in all categories to be judged likely to have a major scientific impact and thus deserve a high impact score. For example, an investigator may propose to carry out important work that by its nature is not innovative but is essential to move the field forward.

III. AUTISM HEALTH NEEDS MEDICAL HOMES PILOT PROJECT

1. Rolling over applications and addressing critiques

Note: This FAQ refers to those applicants who applied to the previous RFA for the Autism Health Needs Medical Homes Pilot Project grants and were not funded.

Q. Can we revise our original submission as we wish, or do we need to re-submit the same document exactly as before and separately address the critiques?

A. You'll want to revise your original application as you wish. It is considered a new application. You'll address the reviewers' critiques in the "Response to Reviewer's Critiques" box.

2. Deliverables

Q. It is my understanding that the deliverables, such as the Project Charter, will be fully developed should funding be awarded. How much information do you need at this time regarding our plans for accomplishing the deliverables? For example, do we need to address every item in the Project Charter, A-K, or every aspect of the HIT Assessment, A-E?

A. Every item of the six project requirements/deliverables does not have to be addressed separately in the application. For example, it would not be necessary to address each item in Deliverable 1 (Project Charter) to show an understanding of the requirement. If the grant is awarded, every item will need to be discussed in the final Project Charter.

However, in describing the approach and plans for accomplishing Deliverable 2 (HIT Assessment) applicants may find it advantageous to describe each item in confirming their understanding of the project requirement. How would you go about gathering the information? Who will be involved? Is any of the information currently available?

For the workflow mapping, it is important to describe your understanding of mapping and the process you would follow to create the "as is" and "to be" maps, including input from staff and others, as appropriate.

In addition, Sections on Organizational Capacity and Readiness to Implement are very important in determining an applicant's ability to achieve the goals, objectives and deliverables of the project as well as the applicant's readiness to design, develop, implement and measure all project requirements.

General information about the applicant's organization (history, current practices and accomplishments) and plans for the proposed medical home should be included in the Section on Organizational Capacity.

Applicants who are funded will complete the Project Requirements, with deliverables, within the two year grant period.

3. HIT Assessment

Q. We are discussing EHRs; however, we do not have an EHR system. Are we required to have EHRs?

A. You are required to complete a HIT assessment and if you are discussing EHRs you should include the status of developing EHRs as one component of your core clinical system.

Q. Regarding the HIT part of the proposal: can some funding be used for creating an IT interface or web interface for means of sharing information between different partners in the project, since as yet there is not universal EHR? Does it have to all be already in place, or can funding be used to refine what might already be available?

Applicants are required to describe the approach and plans for accomplishing the HIT Assessment.

If awarded a grant, the grantee will assess its electronic infrastructure used to communicate and transfer patient information between physicians and other professionals, patients, programs and service agencies.

4. Staff

Q. Biosketch - I plan to include biosketches of PI and key staff. Is it necessary to include a biosketch of the clinical coordinator?

A. You should include the biographical sketch of the clinical coordinator if you describe the role of the person as a member of the core project management team in your description of organizational capacity.

Q. Regarding the field in "Application Summary" who is the "Name of DOH Program Manager Regarding Application"?

A. Martin T. Zanna, MD, MPH

SAGE

Q. I am looking to apply to the Clinical Research Pilot and Translational Research Pilot Projects. Can you please confirm which link I should use to create the application within Sage?

A. Autism Pilot Projects 2017 is the link to use.

Q. It looks as though the biosketches in the Pilot Project application in SAGE have been condensed to one page only (no detail page). Is this correct?

A. Yes, that is correct. The additional support page includes questions that were previously included in the detail page.

Q. In the Pilot Project biosketch section in SAGE I see that there is a page for additional support. I am assuming I am inserting additional support for all of the key professional staff here. Am I reading this correctly?

A. You are correct - Individual one page biosketches and a single page with everyone's additional support information.

Q. Under 'Other Support', my data is exceeding the approved length allotted and I am only up to my 4th person! Can the character length be increased?

A. The character limit cannot be increased for these applications. You can note at the end of the page that the remaining information is included as a miscellaneous attachment (include the name of the attachment).

Q. When I open the SAGE program CAUT17APL I see a combination of letters and numbers that I'm not familiar with, as the Account reference.

A. This is a SAGE generated number. You are in the correct program for the Clinical Research Pilot and Translational Research Pilot Projects.

Q. Can we add the CV's as an attachment vs. filling in the CV grid page on SAGE?

A. The CV grid page on SAGE needs to be filled in. If you need additional space you can attach a file as a "miscellaneous attachment".

Q. Will reviewers access the grant electronically or printed copy (we have graphics which show up differently electronically vs. print).

A. Reviewers will access the grant applications electronically. In addition to completing the narrative questions on SAGE we recommend attaching a complete narrative with graphics, charts etc. as a miscellaneous attachment.

Q. Is a Tax Clearance Certificate a new requirement?

A. The requirement was effective July 1, 2012. All contracted agencies are required to complete an Application for Tax Clearance—Business Assistance and

Incentives http://www.state.nj.us/treasury/taxation/busasst.shtml. A Tax Clearance Certificate will be uploaded to SAGE as a Required Attachment during the application process. Tax Clearance Certificates must be acquired before the application submission due date. Failure to acquire the Tax Clearance Certificate will make the application Non-Responsive. Additionally, a Statement of Gross Revenue or Annual Audit Report is required.

Q. Does the character limit include spaces?

A. Yes, every space counts as a character.