NEW JERSEY GOVERNOR’S COUNCIL FOR MEDICAL RESEARCH AND TREATMENT OF AUTISM
New Jersey Department of Health

Request for Applications

New Jersey Autism Center of Excellence

Funding Opportunity Number: CAUT18ACE

State Fiscal Year 2018

Letter of Intent Due Date: August 16, 2017
Application Due Date: September 14, 2017
Funding

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<th>Funding Opportunity Title</th>
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<td>Estimated Annual Award Amount</td>
<td>Up to $800,000 per year</td>
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<td>Project Period</td>
<td>April 2, 2018-March 31, 2023 (five years)</td>
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<td>Eligible Applicants</td>
<td>Research Qualified Institutions of higher education, public and private non-profit research institutions, in the State of New Jersey</td>
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<td>Notification Date</td>
<td>January 15, 2018</td>
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**Frequently Asked Questions (FAQs):** During the application process, questions may be addressed to [NJGCA@doh.nj.gov](mailto:NJGCA@doh.nj.gov) until September 1, 2017. The answers to questions from applicants will be posted weekly on the Council website at [http://www.nj.gov/health/autism/grant/index.shtml](http://www.nj.gov/health/autism/grant/index.shtml) under “Grant Opportunities/FAQs”.
Introduction

Autism spectrum disorder (ASD) is a group of complex neurodevelopmental disabilities defined by significant impairments in social interaction and communication as well as the presence of unusual or restricted behaviors and interests. These disorders, for which there is presently no cure and only limited treatments, generally have lifelong effects. The Centers for Disease Control and Prevention (CDC) estimates an average of 1 in 68 children in the United States has ASD, as reported in the MMWR Surveillance Summaries, April 1, 2016/ Vol. 65 / No. 3. As part of the same CDC study, the prevalence rate for the New Jersey sites was established at 1 in 41 children, the highest among the sites studied. The prevalence of ASD continues to increase in New Jersey. New Jersey’s higher rates can be attributed in part to increased awareness and detection.

The Governor’s Council for Medical Research and Treatment of Autism (Council) was created by a State appropriation in 1999 and has been issuing research, clinical and educational enhancement grants since 2000. The mission of the Council is to “advance and disseminate the understanding, treatment, and management of ASD by means of a coordinated program of biomedical research, clinical innovation, and professional training in New Jersey.”

As per P.L. 2007, c.174 monies from $1 dollar surcharges on fines and penalties from traffic violations are deposited by the State Treasurer into the Autism Medical Research and Treatment Fund to sponsor the Council to fund autism research and treatment in the State of New Jersey. Currently, the Council funds 27 clinical research grants, 4 basic science research grants and 6 autism medical homes grants.

This Request for Applications (RFA), developed by the Council during their strategic planning process, addresses the requirements of its enabling legislation (P.L. 2007, c, 168, the New Jersey Autism Biomedical Research Act) to establish a Center of Excellence for Autism in the state. The statute defines the scope of activities to be undertaken by the Center including, but not limited to: 1) basic and clinical biomedical research, 2) professional training and continuing education programs for healthcare professionals and 3) public awareness, with the understanding that the work carried out at the Center will be comprehensive and collaborative. It is anticipated that the long-term impacts are expected to improve the lives of individuals with ASD across their lifespan.
Funding Priority

The Council through the New Jersey Department of Health (NJDOH), will fund a New Jersey Autism Center of Excellence (NJACE) to serve as the hub for basic and clinical biomedical research*, diagnosis and treatment of autism spectrum disorder (ASD) in New Jersey. NJACE will support and stimulate research into the causes, diagnosis and treatment of autism spectrum disorder (ASD) in New Jersey and provide a statewide system of training and continuing education programs for health care professionals to improve the clinical care of children, adolescents and adults with ASD. The work carried out at the Center will support the Council’s commitment to advance and disseminate the understanding, treatment, and management of ASD by means of a coordinated program of biomedical research, clinical innovation, and professional training in New Jersey.

*Basic and clinical biomedical research includes, but is not limited to, research in the fields of developmental neurobiology, genetics, psychopharmacology, neuroimaging, immunology, infectious diseases, gastroenterology, epidemiology, endocrinology and health services research.

Below is a summary of the Goals:

Goal 1: Improve clinical care for individuals with ASD in NJ by strengthening knowledge and training of health care professionals in NJ regarding ASD biomedical treatments, diagnosis and prevention.

   a) Provide professional training programs on biomedical treatments, diagnosis and prevention for autism for physicians and other health care and allied health care professionals in the state, including but not limited to Council-funded autism medical homes professionals. The NJACE may identify and implement nationally recognized training programs and/or design programs to meet the specific needs of the target audience(s) (See Appendix). The NJACE may provide stipends for health care professionals enrolled in training programs.

   b) Provide information and continuing education programs on autism for physicians and other health care and allied health care professionals who provide care for patients with autism in the State. For example, the NJACE could sponsor periodic visiting professors, or grand rounds, as a way for a health system to have access to nationally renowned individuals. (See Appendix).

Goal 2: Strengthen Council funded projects by facilitating ongoing communication among researchers, both basic and clinical, and autism medical
homes grantees to discuss progress, lessons learned and challenges, and share best practices.

a) Maintain a communication network among researchers and autism medical homes grantees (i.e., a SharePoint site and/or a listserv) as a vehicle for ongoing interchange of ideas and dissemination of materials, including research methods, important research and treatment advances, funding opportunities, available training and any other significant ASD news.

b) Organize annual meetings of the researchers and autism medical homes grantees to: (1) share research approaches and lessons learned, (2) identify potential areas of collaboration or expansion, and (3) address newly identified areas of research and/or emerging issues impacting autism research and treatment.

c) Develop key criteria for identifying best practices used by the researchers to achieve the goals and objectives in their project plans, and implement a mechanism for sharing these best practices broadly with other researchers, as appropriate. A broad range of approaches could be considered for sharing best practices, from newsletters and conferences to online discussion boards or a page on a NJACE website.

Goal 3: Assist grantees in complying with NJDOH and Council’s grant requirements by providing administrative and technical support.

a) Assist new grantees with administrative issues by facilitating bimonthly conference calls for new grantees during the first year of the grants. This includes developing topical areas and agenda items, providing background information, writing key issues and discussion points, and providing follow up material. The first conference call will be held within a month of grant awards and include a discussion of the responsibilities of the grantees and the NJACE. For subsequent years, the NJACE will facilitate periodic conference calls, as needed. Assist grantees, as needed, with submitting program and/or financial reports to the NJDOH through the System for Administering Grants Electronically (SAGE).

b) Provide technical assistance to grantees, as needed. Grantees requiring technical assistance can (1) self-identify; (2) be identified during the critiques of grant applications by the Scientific Merit Review Panel; and/or (3) be identified by external reviewers during the annual progress review required by the Council for consideration of continuation funding.

The NJACE grantee will:

i) Develop a technical assistance process, including identifying grantees that require additional support to achieve project goals and objectives.
ii) Provide a roster of experts that can provide both on site and telephone technical support to grantees.
iii) Conduct site visits and/or telephone technical assistance calls.
c) Assist grantees who are collecting data from human subjects to share those data via the National Database for Autism Research (NDAR). The NDAR was established by the National Institutes of Health (NIH) and provides a secure bioinformatic platform for scientific collaboration and data-sharing among investigators.

Goal 4: Advance ASD research and treatment in NJ by promoting awareness of ongoing basic and clinical research and medical homes projects, emerging clinical issues, and research opportunities to relevant audiences including students, families, clinicians and scientists interested in ASD research.

a) Promote ongoing research to the public and ASD community, and facilitate human subject recruitment for Council-funded projects.
b) Foster community engagement by enabling two-way communication between the ASD community in NJ and ASD grantees to improve ongoing and new projects. These activities should inform grantees about community concerns and feasibility of future studies while sharing with the community current research avenues and plans for future studies.
c) Stimulate cutting edge ASD research and treatment in NJ by organizing two state-wide conferences (over 5 years) on ASD research and treatment featuring national and state leaders in ASD research and treatment. Such conferences would present best practices in ASD research, highlight important clinical issues and emerging research areas, attract new researchers to the field, and facilitate collaborations both between researchers and clinicians, and between new and established ASD researchers.

NJACE Leadership
The NJACE will designate a nationally recognized autism researcher as the Program Director/ Principal Investigator (PI) whose background demonstrates strong administrative and academic leadership. The PI has overall project responsibility and serves as a liaison to the Council and the Executive Director. In addition to the PI, the NJACE staff will include: 1) a Scientific Director with responsibility for scientific research oversight and assistance, and 2) a Clinical Liaison to develop and implement professional training and education programs as well as provide oversight and technical assistance to autism medical homes grantees. Both the Program Director/PI and Scientific Director’s roles may be performed by the same person; however, the applicant would have to demonstrate that the PI has the extensive skills and experience necessary to perform these roles. If separate teams or departments at a large institution wish to apply for and receive grants under both the NJACE grant program
and other Council funded grant programs, there can be no overlap of personnel or duties between the NJACE and other Council funded grants.

II. Funding Amount, Availability and Eligibility Requirements

Funding Amount:
A total of up to $4,000,000 (up to $800,000 per year) will be made available for the five years of the program. The award will begin on or about April 2, 2018.

Funding Availability:
The award is subject to the availability of funds to the Department. The grantee recognizes and agrees that continuation of funding under a grant is expressly dependent upon the availability of future funds to the Department appropriated by the State legislature from state or federal revenue or such other funding sources as may be applicable. The Department shall not be held liable for any breach of agreement due to absence of available funding appropriation. The Council shall reserve the right not to fund any grant to the maximum amount or not to fund any grant program at all.

Multi-year Award & Progress Report Requirements:
Multi-year awards are made through one-year contracts. Each yearly award within the multi-year period will be contingent upon the availability of funds. Support for the continuing years of the grants is contingent upon submission and approval of an annual comprehensive progress reports. All progress reports must detail the actions towards meeting the grant requirements. The NJACE will meet the grant requirements or clearly demonstrate how they are moving towards achieving those requirements, as a condition of funding for the following year. Progress reports must be favorably reviewed by a NJDOH Review Panel and be recommended to the Council for continued funding. The Council shall reserve the right to bring in outside reviewers to assess whether progress is adequate and, as may be necessary, design a remediation plan. A final progress report is required within three months of termination of the grant.

Applicants shall adhere to the Council’s Code of Ethics which can be found at www.nj.gov/health/autism. In addition, applicants shall adhere to all applicable State and Federal laws and regulations governing the privacy, security and confidentiality of all research and participant’s health information. The laws and regulations include, but are not limited to, the Health Insurance Portability and Accountability Act of 1996 (HIPAA) – Privacy and Security Rules and the Patient Safety and Quality Improvement Act of 2005 (PSQIA) – Patient Safety Rule. Lastly, all applicants shall comply with applicable Federal Cost Principles and Scientific Research governing human participants.
Eligibility:
Qualifying Individuals:
Individuals with the skills, knowledge, and resources necessary to carry out the proposed program as the Principal Investigator are invited to work with their organizations to develop an application. Applicants must be affiliated with an academic institution, research organization or public or private non-profit entity, preferably an academic medical institution, located in the State of New Jersey with a demonstrated capability to conduct grant funded research. The Council shall not award grants to unaffiliated individuals. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are encouraged to apply. Individuals of any nationality or citizenship status may apply provided they hold employment or affiliate with a qualifying research entity, as described below.

Note: If separate teams or departments at a large institution wish to apply for and receive grants under both the NJACE grant program and other Council funded grant programs, there can be no overlap of personnel or duties between the NJACE and other Council funded grants.

Qualifying Entity:
Public and private non-profit research entities in the State of New Jersey may apply under this program. A qualifying research entity is defined as any academic institution, research organization, public or private non-profit entity, preferably an academic medical institution, located in the State of New Jersey, with a demonstrated capability to conduct and monitor grant funded research. In no case, can an individual be a qualifying research entity. The qualified research entity shall have established procedures to receive and administer Federal and State grants, including a Grant Administrative Office (or equivalent) that is responsible for overseeing grant programs, and procedures for the protection of human subjects as regulated by the NIH and an Institutional Review Board (IRB) that will approve proposed research activities.

Proof of Eligibility:
Applicants are required to submit financial documents, in accordance with the NJDOH Cost Controlling Initiatives and Terms and Conditions. Failure to provide required documentation by the date of the application submission shall result in the application being deemed non-responsive. Please attach the requested documents in Word or PDF to your application through the NJDOH System for Administering Grants Electronically (SAGE):

1. Valid Internal Revenue Service (IRS) 501(C) (3) tax exempt status.
2. Statement of total gross revenue and/or annual report (if applicable).
3. Tax Clearance Certificate is to be submitted – Applications for Tax Clearance
can be obtained at http://www.state.nj.us/treasury/taxation/busasst.shtml.

Summary: Criteria for Funding

Application:
The application shall be evaluated, and funding will be determined, based on the following criteria:

1. Address the details for each of the four goals including a comprehensive workplan that will demonstrate progress.
2. A complete and accurate application.
3. Documentation of the applicant’s ability to provide a New Jersey Autism Center of Excellence.
4. Budgeted line-items that are reasonable and necessary to provide a New Jersey Autism Center of Excellence.
5. Complete and supported application narratives.

Letter of Intent:
A Letter of Intent is required and due by August 16, 2017. Although a Letter of Intent is not binding and does not enter into the review of a subsequent application, the information that it contains allows the Council staff to estimate the potential review workload and plan the review.

The letter of intent must include the following information:

1) Descriptive title of proposed project
2) Name, address, email and telephone number of the Principal Investigator
3) Participating institutions and organizations
4) Title of the funding opportunity – CAUT18ACE
5) Overview of project (2-3 pages) – Goals, aims, activities and evaluation

The letter should be sent to NJGCA@doh.nj.gov. If you do not receive an acknowledgement of receipt within 2 business days, please call 609-633-8740.

Proposal Submission and Delivery:
To be considered, Applicant proposals must be responsive to all the requirements of this RFA. Incomplete grant applications will not be considered and shall be disqualified. All proposals must be submitted via the NJDOH System for Administering Grants Electronically (SAGE) no later than 3:00 PM on September 14, 2017.

Refer to “Instructions for On-line Grant Applications” under “Grant Opportunities” on the Council’s website (www.nj.gov/health/autism) for the date the SAGE application will be available. In the meantime, the narrative questions and a list of required content are included in this RFA.
In addition, the Council must receive from the applicant one hard copy of the application (signed original) at the Council’s office by 3:00 PM on September 19, 2017. No exceptions will be made. Please use the following address for all regular and overnight mail deliveries:

New Jersey Department of Health
New Jersey’s Governor’s Council for Medical Research and Treatment of Autism
225 East State Street
Second Floor-West
PO Box 360, Trenton, NJ 08608

1. SAGE
The Council will only accept for review applications submitted electronically through the New Jersey System for Administering Grants Electronically (SAGE) at www.sage.nj.gov. The Council will not accept grant applications sent by telefacsimile. After an applicant logs on to the SAGE, the applicant’s Authorized Official must authorize the applicant as an approved user and assign the applicant to the grant before the applicant can access the application. Before logging on to SAGE applicants should refer to “Instructions for On-line Grant Applications” under “Grant Opportunities” on the Council’s website (www.nj.gov/health/autism). For the grant applications, character limits for the proposal abstract and proposal narrative are included in SAGE. To ensure equity among applications, character limits cannot be exceeded. Applicants should be cautious while utilizing the cut and paste function of most word processing programs to transfer text into narrative boxes within the SAGE application. The SAGE will not recognize certain formatting, including tables, graphs, photographs, bullets, certain scientific notations and tabs. In addition to completing the text boxes in SAGE, it is recommended to attach the full proposal (abstracts and narrative) as a Word or PDF document with tables, charts and illustrations as a “Miscellaneous Attachment.” In many SAGE pages a “View PDF” button will be available that will automatically create a PDF. These dynamic PDFs can be printed or saved to your computer for reference. It is useful to review the PDF files for accuracy prior to submitting the application electronically.

RFA Required Narrative & Questions
Organization Information: Provide information on your organization’s mission, structure, and scope of current research and education activities. For the research activities, include the sources and amount of funding for autism research during the past 5 years and topical areas of research related to autism. For the education activities, include professional training and continuing education programs related to autism or similar conditions, and community engagement. Describe how these contribute to the ability of the organization to conduct the aims of the NJACE and address the
expectation that, over the cumulative 5-year period of the award, the award will result in improving the lives of individuals with ASD across their lifespans. Include an organization chart in “Miscellaneous Attachments.”

**Management:** Describe the qualifications of the core team including evidence of strong administrative and academic leadership as a nationally recognized autism researcher (Program Director/PI), expertise in the oversight of scientific research projects (Scientific Director) and expertise in the development and implementation of professional training on biomedical treatments, diagnosis and prevention of autism and continuing education programs on the latest advances in biomedical research on autism for physicians and other healthcare providers (Clinical liaison). Describe the qualifications of the Clinical Liaison to provide oversight and technical assistance to autism medical homes grantees. Highlight staff who will be responsible for evaluation of the program and the specific aims.

Note: It is possible the Program Director/PI and Scientific Director’s roles could be performed by the Program Director/PI; however, the applicant would have to demonstrate that the PI has the extensive skills and experience necessary to perform both roles.

**Goal 1: Improve clinical care for individuals with ASD in NJ by strengthening knowledge and training of health care professionals in NJ regarding ASD biomedical treatments, diagnosis and prevention.**

a) Describe plans to provide professional training programs on biomedical treatments, diagnosis and prevention for autism for physicians and other health care and allied health care professionals in the state. How will specific audiences be targeted? How will the professional training programs reflect the specific needs of the target audiences? How will the Center choose to implement existing programs and/or develop additional programs? Will the NJACE provide stipends for health care professionals enrolled in training programs? How will the success of the trainings be evaluated? Briefly describe prior experience.

b) Describe plans to provide information and continuing education programs on autism for physicians and other health care and allied health care professionals who provide care for patients with autism in the State. How will the topics be chosen? What forms will the continuing educations programs take? How will the success of these efforts be measured? Briefly describe prior experience.

c) Distinguish among programs designed to provide basic information (knowledge), positive interactions with persons who have autism (attitudes) and those to increase proficiency in professional interactions (skills). Briefly summarize prior
experiences in developing and evaluating professional training and continuing education programs.

Goal 2: Strengthen Council funded projects by facilitating ongoing communication among basic and clinical researchers and medical homes grantees to discuss progress, lessons learned and challenges, and share best practices.

a) What kind of a communication network will be developed and maintained to stimulate the interchange of ideas and dissemination of materials among grantees? How will the success of these efforts be measured? Briefly describe prior experience.

b) Describe plans to organize annual meetings of the researchers and medical homes grantees to (1) share research approaches and lessons learned; (2) identify potential areas of collaboration or expansion; and (3) address newly identified areas of research and/or emerging issues impacting autism research and treatment. How will the success of these efforts be measured? Briefly describe prior experience.

c) How will key criteria be developed for identifying best practices used by the researchers and the autism medical homes grantees to achieve the goals and objectives in their project plans? What is the mechanism for sharing these best practices broadly with other researchers and stakeholders, as appropriate? Briefly describe prior experience.

Goal 3: Assist grantees in complying with NJDOH and Council’s grant requirements by providing administrative and technical support.

a) Describe plans to facilitate conference calls for Council-funded grantees. Briefly describe prior experience.

b) Describe plans to provide technical assistance to grantees. How will the technical assistance process be structured? How will the Center identify and reach out to grantees who require additional support to achieve project goals and objectives? How will the roster of experts be identified, recruited and compensated? Briefly describe prior experience.

c) How will the Center assist grantees in sharing human subject data via NDAR? Briefly describe prior experience.

Goal 4: Advance ASD research and treatment in NJ by promoting awareness of ongoing basic and clinical research and autism medical homes projects, emerging clinical issues and research opportunities to relevant audiences including students, families, clinicians and scientists interested in ASD research.
a) Describe plans to promote ongoing research. How will various audiences be reached? How will efforts facilitate human subject recruitment? How will success be measured? Briefly describe prior experience.

b) Describe plans to enable two-way communication between the ASD community in NJ and grantees to improve ongoing and new Council funded projects. How will these programs inform grantees about community concerns and feasibility of future projects? How will these programs provide the ASD community information about current projects and plans for future projects? How will the improvements in research, treatment and community awareness be measured? Briefly describe prior experience.

c) Describe plans to organize two state-wide conferences (over 5 years) on ASD research and treatment featuring national and state leaders in ASD research and treatment. How would such conferences present best practices, highlight important clinical issues and emerging research areas, attract new researchers to the field, and facilitate collaboration between researchers and clinicians, and between new and established ASD researchers? How will the stimulation of cutting edge ASD research be measured? Briefly describe prior experience.

Project Work Plan: Incorporate the approaches for Goals 1-4 into a project work plan. Provide a brief description of the work plan and attach the following details of the work plan as a “Miscellaneous Attachment” in SAGE: Use a timeline or chart that includes each activity described in the goals. Include quarterly and annual reports and evaluation (see below) in the timeline or chart. Identify responsible staff and partners, proposed outcome, intended impact and how the activity’s outcome and impact will be evaluated. As appropriate, identify meaningful support and collaboration with key stakeholders in planning, designing and implementing all activities.

Evaluation of the long-term impact of the NJACE: Because of the cumulative 5-year period of the award, how will improvements in the lives of individuals with ASD be measured? Describe the plan for the Center’s performance evaluation and provide details as a “Miscellaneous Attachment” in SAGE. The plan should monitor ongoing processes and progress toward the long-term goals and aims of the Center. Include descriptions of the inputs (organizational profile, collaborating partners, key staff, budget and other resources), key processes and expected outputs and outcomes.
Application Review Information

Review and Selection Process:
All proposals will be reviewed in accordance with the Grant Review Process set forth herein. The determination of grant awards will be made through a two-step review process:

1. Administrative Review (Council office)
Upon receipt, all grant applications will be reviewed by the Council office for compliance with all applicable New Jersey State statutes and regulations, and to ensure completeness and accuracy. In the event a grant application needs correction due to a budgetary issue, the applicant will be contacted to provide a revised budget. In the event the Council office determines that an application does not meet the administrative requirements, the application will be denied, and will not be forwarded for independent scientific merit review.

2. Scientific Merit Review (Independent Scientific Merit Review Panel)
Members of the Independent Scientific Merit Review Panel will convene to evaluate the grant applications. The Panel will consider and score the applicant’s response to each of the narrative questions in the determination of the merit of the NJACE proposal. An overall impact score will be assigned to each application reflecting the likelihood the Center will successfully accomplish the goals of the project while supporting the mission of the Council. The results of the review will be forwarded to the Council, through the Executive Director, for final review and action. The Scientific Advisory Committee (SAC) will review the results of the Review Panel and may provide additional advice to the Executive Director and the Council. Grants triaged by either Administrative Review and/or the Independent Scientific Merit Review Panel will not be forwarded to the Council, and will not be funded. The authority to authorize or not authorize grants is fully vested in the Council per New Jersey statute P.L. 2007, c.168 (NJSA C.30:6D-60).

VI. AWARD ADMINISTRATION INFORMATION

1. Award Notices
All applicants including Principal Investigators and organizations/institutions will be formally notified of the outcome of his/her application at the conclusion of the selection process, anticipated to be no later than January 15, 2018. At that time, formal notification will be made to the institution of the successful applicant and a contract will be initiated shortly thereafter by the Council with a project start date of approximately April 2, 2018. Non-funded applicants also will be notified. There is no appeal process.
2. Reporting
The NJACE will provide quarterly and annual progress reports to the NJ Department of Health. The Council's Executive Director will provide reports to the Council upon request. Twice during the first year and every year thereafter the Center will draft a questionnaire for its own self-evaluation. Following approval by the Council's Executive Director, the Center will send these questionnaires to the researchers. The responses from the researchers will be sent to the Council's Executive Director, who will use this data as an adjunct to monitor the NJACE’s performance. A summary of the results will be provided to the NJACE to ensure improved performance.
VII. APPENDIX

Appendix: Examples of existing resources for training healthcare providers

The Certified Autism Specialist (CAS) offered by International Board of Credentialing and Continuing Education Standards at http://www.certifiedautismspecialist.com/

The Interdisciplinary Technical Assistance Center (ITAC) on Autism and Developmental Disabilities at http://www.aucd.org/itac/template/index.cfm


The Accreditation Council for Graduate Medical Education (ACGME) at https://www.acgme.org

Alliance for Continuing Education in the Health Professions at http://www.acehp.org

The Cleveland Clinic Autism Research Institute at http://www.clevelandclinicmeded.com/online/autism-spectrum-disorders/