



Request for Applications



Autism Treatment Network 2010 Cycle

Deadlines:

Letter of Intent: April 9, 2010, 11:59 p.m. (EST)

Application: July 16, 2010, 11:59 p.m. (EST)

Other Important Dates (subject to change):

Invitations for Full Applications: early May 2010

Peer review panels: Fall 2010

Notification: December 2010

Grant start date (earliest): January 2011

Funding Period: January 1, 2011-December 31, 2013

Section I. Introduction

Background

The mission of Autism Speaks is to improve the lives of individuals with autism spectrum disorders (ASD) and their families. The Autism Treatment Network (ATN), a program of Autism Speaks, is dedicated to providing comprehensive, multidisciplinary medical care to children and youth with ASD within their local communities. As a system, the network is committed to continuously improving the quality of care through the application of quality improvement methods and the performance of clinically relevant research.

ASDs are a group of complex neurodevelopmental disorders characterized by impaired social interaction, delayed and disordered language, and repetitive/stereotypic behaviors. Current prevalence studies show that approximately one out of every 110 children in the U.S. is diagnosed with an ASD. Many individuals with ASD have co-morbid medical conditions including seizures, sleep problems, gastrointestinal (GI) disorders, and metabolic conditions. When left untreated, such medical conditions may compromise not only physical health, but also behavioral, developmental, and educational outcomes of individuals with ASD. Unfortunately, these children and their families face many barriers in accessing appropriate healthcare and are less likely than children with mental retardation or other special needs to obtain the specialty medical care that they need.

The barriers to medical care for children with ASD include the lack of primary and specialty health care providers with the training and experience to identify and assess medical conditions appropriately in this

population. Even when medical conditions are recognized, physicians are often reluctant to treat patients with ASD because there are few standards to guide their care. Treatment has tended to focus on the behavioral aspects of ASD, while medical conditions have not received adequate attention. The ATN was established to address these issues by creating a network of high quality medical care centers engaged in a systematic approach to improving the care of children with ASD and the dissemination of practice guidelines into wider clinical practice. The ATN's strengths include an established collaborative infrastructure across multiple institutions, a registry of well-characterized children and adolescents with ASD receiving ongoing care at participating sites, a data coordinating center and clinical coordinating center, and considerable scientific and clinical experience to support research on evidence-based practices for interventions, policy development, and dissemination.

The ATN's clinical work has focused on the development of a standard assessment protocol and the development of clinical guidelines for children with ASD in the areas of sleep, GI, neurology, and pharmacological treatments. The ATN's primary clinical research agenda has similarly focused on sleep problems, gastrointestinal disorders, nutrition, and neurology. Increasingly the ATN is focused on the development, dissemination, and implementation of a common model of care built on the framework of the Chronic Care Model. For more information on ATN guideline and research activities, go to www.autismspeaks.org/airp. For more background and a description of the ATN go to www.autismspeaks.org/atn.

Purpose

Autism Speaks requests applications to participate in the Autism Treatment Network (ATN). Specifically, this request solicits applications for ATN Centers of Clinical Excellence (CCE). The network consists of hospitals and academic medical centers with extensive experience in the diagnosis, assessment, and medical treatment of children and adolescents with ASD. Applications are encouraged from institutions that have an established autism clinical program that provides on-going, comprehensive, multidisciplinary medical care for children and adolescents with ASD.

Participation in the ATN requires delivery of multi-disciplinary, coordinated medical care including use of the [ATN Assessment Battery](#) as part of the standard of care at the clinic. The multi-disciplinary team should include pediatricians, neurologists, child psychiatrists, and psychologists, as well as experts in sleep medicine, pediatric gastroenterology and medical genetics/metabolics, who have a clinical background in autism as well as a record of meaningful and committed multidisciplinary collaboration.

ATN sites engage in collaborative network-wide activities to continuously improve quality of care. All sites participate in multi-site collaborations to develop evidence-based practice guidelines and tools to support their implementation. Sites commit to both implementing these guidelines, and more broadly, to improving their systems through data sharing and transparency, engagement of families in improvement, and changing structures and processes to achieve better outcomes. Centers must be committed to participating in the further development and refinement of the ATN Assessment Battery. ATN sites enroll children evaluated at the clinic into the ATN Registry and have the resources to undertake systematic data collection through a web-based data management system to support quality improvement efforts.

In addition to these core activities, sites may participate in independently-funded clinical research supportive of the ATN mission. All sites must therefore demonstrate a capacity and expertise to participate in multi-site clinical research.

Section II. Awards and Funding Guide

US \$140,000 per year for up to 3 years inclusive of 15% indirects.

Use of Funds:

This RFA is aimed at institutions that have an established autism clinical program that provides on-going, comprehensive, multidisciplinary care for children and adolescents with ASD. For this reason, support through this grant is not intended to be used for providing clinical care except in unusual cases. Funds are primarily intended to support personnel who are coordinating data collection and entry into the ATN registry, clinical staff participation in network activities such as guideline development and quality improvement, and, if necessary, unreimbursed clinician time. The funds are NOT intended to provide primary salary support for the PIs or to support clinician activities that are reimbursable.

Allowances and restrictions to funding allocations are:

1. Project coordinator. Recommended 50%-100% effort.
2. Data personnel for data entry and/or data coordination
3. Funds may also be allocated to cover partial effort of the PIs and Co-PIs for their participation in network activities. FTEs for PIs and Co-PIs are limited to 15% effort.
4. Medical and clinical specialists may be supported for their participation in network committees through salary support ranging from 2% to 5% effort depending on the individual's level of participation on the committee.
5. Funds may be allocated to cover partial effort of clinical personnel providing clinical services that are not reimbursable at an institution such as staff time to conduct ADOS or cognitive assessments. Percent effort in such cases is limited to 25%.
6. Funds may be allocated for other support personnel, consultants, supplies, travel, patient costs, assessment tools, small equipment and miscellaneous expenses. Equipment allocations cannot be used for large or permanent equipment purchases over \$5000, or equipment that should and would otherwise be provided by the institution as part of the clinic infrastructure.
7. Salaries are limited to current NIH salary caps of US \$199,700.00.
8. Maximum of 15% can be devoted to indirect costs, included in total amount.

Funding Allocations and Disbursement: Institutions will be paid on a capitated (per subject) basis based on enrollment of patients into the ATN Registry. Sites will receive 60% of their budget upfront and will be paid on a quarterly basis thereafter once the site meets 50% of its target enrollment.

A detailed budget must be included with the full application detailing how the funds will be allocated at the site. A budget is NOT required for the Letter of Intent. Information on the budget forms and budget justification requirements is provided in Section VI.F.

Cost Sharing or Matching: None. While institutions are not expected to match costs, it should be understood that Autism Speaks funding is not intended to cover or support all costs for implementing the clinical model.

Section III. Eligibility

Applicants must meet these requirements in order for their applications to be considered. Autism Speaks reserves the right to terminate any application that does not comply with the policies and procedures prescribed in the RFA and other application instructions at any time during the application and review process.

A. Eligible Institutions

Hospitals and academic medical centers are eligible. Applications may include more than one institution but a single institution must be identified as the applicant institution.

Applications from multiple institutions that are geographically distant, and do not share formal affiliations and infrastructure must provide a clear justification for the collaboration with respect to

benefits for the families, and an explanation of how they will ensure efficient and effective communication between institutions.

The institution has an existing autism clinical program that provides on-going treatment services to individuals with ASD (not only diagnostic/research assessments).

The clinical program serves at least 300-400 new patients with ASD per year and has the capacity to enroll at least 100 individuals with ASD in the ATN Registry.

Preference is given to sites that have established relationships with primary care and other community providers to extend the reach of the ATN Care Model to a larger population of affected children and their families.

B. Eligible Individuals

1. The lead Principal Investigator (PI) serves as the Site Director for ATN.
2. PIs/Co-PIs must have an M.D. and/or Ph.D., and at least one Co-PI must have an M.D. if the lead PI does not.
3. Sites are required to have at least one Co-PI.
4. Background Requirements:
 - a. PIs must be senior-level clinicians at the institution charged with oversight of clinical operations and have the authority to effect change in care as needed.
 - b. The PI must have a key decision-making position within the institution's clinic for autism services (e.g. Director, Co-Director, Associate Director).
 - c. PIs/Co-PIs must have substantial clinical experience with children with ASD and their families.
 - d. PIs and Co-PIs must demonstrate a successful track record of creating and coordinating a multi-disciplinary team.
 - e. At least one of the PIs should have:
 - i. Demonstrated experience in clinical research including a proven record of federal funding (e.g. NIH, CDC.)
 - ii. Demonstrated experience with clinical quality improvement endeavors
5. PIs and Co-PIs may be from any of the core ATN specialties listed below in III.D. Medical leads are typically developmental pediatricians, pediatricians, pediatric neurologists, or child psychiatrists.

C. Institutional Support

Sites must demonstrate institutional support for their participation in the network and are required to submit a Letter of Support with their full applications from the head of the division or department with oversight over the clinic. It is expected that the institutional leadership will support:

1. The philosophical mission of the ATN
2. The applicant's implementation of the ATN clinical model at the institution
3. The applicant clinic's participation in network-wide quality improvement efforts and guideline development
4. The implementation of changes to the standard of care, as needed
5. The integration of the ATN data forms into the site's electronic or other medical record

Institutional support may be demonstrated in several ways: financially through personnel allocations, material resources, facilities or equipment; or through cross-departmental collaboration and/or shared resources.

D. Clinical Infrastructure: ATN Care Model

Applicant institutions must be able to provide access to a comprehensive, coordinated, multi-disciplinary care model for children with ASD. Sites must commit to a common standard and model of care across their patient population, and not specifically only to patients enrolled in the registry.

1. The overall clinical approach must be consistent with the criteria for the chronic care model. The model includes the elements outlined below:
 - a. Definition of child-specific clinical goals
 - b. Means of actively monitoring progress in addressing patient's specific problems, through planned follow up, with clearly defined clinical goals and outcomes
 - c. Use of appropriate practice guidelines in care when they exist (with monitoring of adherence to them)
 - d. Education of parents about ASD and existing available treatments, including those for associated medical issues
 - e. Coordination of care, including additional medical care as well as other treatments and services (specialized therapies, behavioral interventions, community and educational interventions and resources)
 - f. Involvement of parents in decision-making for their child

2. The clinical approach should include a multidisciplinary team, including a range of professionals necessary for the care of the child.
 - a. The applicant site must demonstrate access to and established collaborations among the following medical sub-specialties:
 - i. Developmental Pediatrics
 - ii. Pediatric Neurology
 - iii. Child/Clinical Psychology
 - iv. Pediatric Sleep Medicine
 - v. Pediatric Gastroenterology
 - vi. Medical Genetics/Metabolics
 - b. The following specialty areas are not required but are considered positively:
 - i. Child Psychiatry
 - ii. Pain
 - iii. Immunology
 - iv. Endocrinology
 - c. Ancillary Care: Applicants must demonstrate access to ancillary care services including Occupational and Physical Therapy, Speech-Language Therapy, and Nutrition.
 - d. Nursing Team: Applicant sites should have nursing staff with experience working with the ASD population, and preferably clinical quality improvement activities.
 - e. Clinicians must be board certified (or licensed in the case of psychology) in their respective specialties.
 - f. All clinicians must have substantial clinical experience with children with ASD and their families. If the site is bringing on specialists new to the autism field, the applicant must provide a description of the type of autism-specific mentoring and training the specialist will receive.
 - g. Each site must identify at least one representative in each of the six required specialties (above in 2a.) who will have partial time dedicated to participating in network-wide committee, quality improvement and guideline activities. Representatives from the nursing team and support staff may be needed to participate in quality improvement projects.

3. Support staff:
 - a. Applicants must demonstrate availability of the following support staff:
 - i. Project Coordinator (site or clinic coordinator) with experience in project management for multi-site patient registry/research collaborations and quality improvement projects

- ii. Data support staff with a track record of coordinating data entry and quality for multi-site collaborations
 - b. The ideal site will also have access to social workers/family advocates, resource specialists, and care coordinators.
4. Successful applicants have the capability and commitment to integrate the ATN Assessment Battery into their standard of care for children with ASD. The ATN Assessment Battery and the Forms Submission Schedule which outlines which assessments are repeated for annual visits can be downloaded from:
http://www.autismspeaks.org/science/programs/atn/atn_physicians_researchers.php

It should be noted that the ATN Battery, the ATN Custom forms, and collection schedule are subject to an annual review and may be subject to revision.

5. Autism Diagnostic Observation Schedule (ADOS): It is preferable for all clinicians administering the ADOS to be research reliable. Minimally, the applicant must have a lead individual who is research reliable via UMACC or national-level UMACC compatible training (regional WPS training or local training by a certified trainer), who provides oversight and with whom all local ADOS administrators are locally reliable.

E. Network Collaboration

1. ATN Registry
 - a. All sites are committed to enrolling a minimum of 100 children per year into the ATN Registry and entering data on annual follow-up assessments for up to 3 years (third year of follow-up contingent on the site's continuation in the network).
 - b. Sites are required to submit select data through the ATN's web-based data capture systems to support overall goals to improve the quality of care. **As noted above, applicants should be aware that the ATN Battery, the ATN Custom forms, and required data for inclusion in the Registry are subject to an annual review and may be subject to revision.**
 - c. Data tracking, cleaning, and analysis will be coordinated for all sites by the Data Coordinating Center.
 - d. All sites must meet data quality requirements and enrollment targets.
2. Quality Improvement/Guideline Development Activities
 - a. Sites must commit to transparency across the network in sharing their performance data; in identifying common and individual priorities for quality improvement; and in working collaboratively to continuously improve processes and outcomes of care for all children they serve. This will include the creation of site specific, multidisciplinary quality improvement teams and their participation in network-wide quality improvement activities (including benchmarking and process improvement). This may involve the collection of targeted data on children at the clinic who are not enrolled in the registry. Teams and sites participating in quality improvement activities are expected to report frequently (typically monthly) with both data and progress report information to track progress towards quality improvement aims.
 - b. ATN sites participate in multi-site collaborations to develop evidence-based practice guidelines and tools to support implementation of these guidelines, including pilot testing.
 - c. Centers must also participate in the further development and refinement of the ATN Assessment Battery.
3. Committees
 - a. The PI serves as the site's representative on the ATN's Clinical Operations Committee. The Clinical Operations Committee provides guidance for the ATN's clinical and scientific activities and provides leadership for the operation of the network sites.

- b. Clinicians and specialists serve on the ATN subspecialty committees. All sites must provide an appropriate representative to the committees. Current committees include: Neurology/Genetics/Metabolics, Sleep, GI, Behavioral Science and Psychopharmacology.
- c. The site coordinator participates in the Site Coordinator Committee.
- d. The ATN will be establishing two new committees in the next grant cycle: a Quality Improvement Committee and a Family Advisory Committee. Sites should identify appropriate individuals to serve on these committees. See Section VI.B.4 “Personnel” for descriptions of committee member qualifications and responsibilities.
- e. Approximate time commitment for the committees are as follows:
 - i. Member: 2 hours/month on average, 25 hours/year
 - ii. Chair*: 3 to 4 hours/month on average, 35 to 50 hours/year

**Chair positions are determined by invitation from the ATN leadership and consensus of the committee members.*

Applicants should see Section VI.B. 4: “Personnel” for a complete description of the roles and responsibilities of key personnel for clinical and network activities.

F. Research Capacity

1. Applicants should demonstrate capacity and interest to conduct clinical research. Sites should demonstrate capability to conduct multi-site intervention trials.
2. Sites should demonstrate evidence of participation in other multi-site research networks such as having an on-site Clinical and Translational Science Award (CTSA) facility.
3. Capacity to collect and store biomaterials is not required but is considered positively.

Section IV. Submission Requirements

A. General Information

1. All applications must be submitted electronically through the Autism Speaks Grants Administration System.
2. Note that this is a new system and all are encouraged to review the layout and format of the grants administration system at least one month prior to the application deadline.
3. In order to get access to the new grants system, please email your contact information (name, institution, degree, office address, phone number) from your institutional email to grantadmin@autismspeaks.org. You will receive all needed information by return email. **NOTE: You will need to request access to the new system even if you have previously applied for funding from Autism Speaks.**
4. The lead PI has the responsibility to register and complete the application on the behalf of the Co-PIs. Only one person can log-in, access and edit the application. The PI is the individual who will take responsibility for all fiscal matters, reporting requirements, deliverables, and scientific matters related to the grant.
5. An LOI must be submitted and approved before a full application can be completed. All LOI review decisions are final.
6. Only applications electronically submitted will be accepted for review. Applications submitted by regular mail or by email will not be reviewed or acknowledged.
7. It is the applicant’s responsibility to ensure that submissions in whole or in part are in compliance with the policies and procedures outlined in the RFA.

Autism Speaks reserves the right to terminate any application not in compliance with the policies and procedures prescribed in the RFA at any time during the application or review process. This includes late or incomplete applications.

Forms and Background Documents

Background documents can be found at:

http://www.autismspeaks.org/science/programs/atn/atn_physicians_researchers.php

Background documents include:

- A. ATN Assessment Battery list
- B. ATN Forms Submission Schedule (outlines which forms are captured at follow-up)
- C. Request form to obtain copies of the ATN Custom Forms

Application materials and required forms are posted on the Autism Speaks grant system page. You MUST request a log-in for the grants system in order to have access to the application and application materials. In order to get access to the new grants system, please email your contact information (Name, institution, degree, office address, phone number) from your institutional email to grantadmin@autismspeaks.org. You will receive all needed information by return email.

B. Submitting the Letter of Intent

1. Log in to the Autism Speaks grant system per the instructions sent by email.
2. Click on “Start New Application”, then on “Autism Treatment Network”
3. “Project Name”: Enter the title of your project as “ATN 2010- [INSERT SITE NAME or ABBREVIATION]” (Less than 50 characters)
4. Click “Save as Draft” often to save your work.
5. Click on “Submit Form” at the bottom of the page when LOI is complete.
6. LOI forms can be completed and submitted by the applicant.

C. Submitting the Full Application

1. Log in to the Autism Speaks grant system per the instructions sent by email. If your LOI has been approved, then the full application will be available. Click on the ‘Edit Application’ link and follow the instructions.
2. Click “Save as Draft” often to save your work.
3. When the application is complete, the Responsible Official for your institution must log into the system in order to complete the submission of the application.
4. It is the applicant’s responsibility to contact their Office of Sponsored Projects (or the equivalent) to identify the Responsible Official (RO) for this application. The Responsible Official is someone from the Office of Sponsored Projects (or its equivalent), who will review and submit the final portion of the application. Their submission is their approval of the application on behalf of the institution. LOI forms can be completed and submitted by the applicant. Full applications can only be submitted by the RO. Applicants should email the RO’s contact information to grantadmin@autismspeaks.org. The RO will receive login information by email.

Section V. Detailed Instructions for the Letter of Intent

A checklist of required items is provided in Appendix 1.

A. Online Site Information Form (Letter of Intent)

Once you have entered your project information in the grants system, you will see the LOI online form. The first section consists of questions that you will need to enter online. The information required is below. It is highly recommended that you gather and store the information in another format as a back-up.

1. Applicant Information
 - a. Collaborating institutions, if applicable
 - b. Specialty of PI [*The PI is the individual who will take responsibility for all fiscal, reporting, deliverable, and scientific matters related to the grant*]
2. Personnel. Complete the Personnel List and upload. The following information is requested. A link to the Personnel List can be found on the grant system website once you log-in.
 - a. Clinical Personnel: Information on the PI, all Co-PIs and each of the required specialists (GI, sleep, neurology, genetics/metabolics, pediatrics/psychiatry, and psychology) not already named as one of the PIs. This includes:
 - i. Name and affiliation
 - ii. Specialty
 - iii. Confirmed board certification in respective specialty
 - iv. Title(s)
 - v. Number of years working with ASD population
 - vi. Total percent effort on ATN
 - b. Support Personnel: Information on the project coordinator (required for LOI), data support staff (required for LOI), social workers, care coordinators and other support staff. This includes:
 - i. Name and affiliation
 - ii. Title(s)
 - iii. Certification, if applicable (clinical research associate/coordinator)
 - iv. Years experience with ASD patient population
 - v. Years experience with multi-site projects
3. Patient Information
 - a. Patient Volume
 - i. Number of clinics serving patients with ASD
 - ii. Total number of ASD patients served annually (new and on-going)
 - iii. Total number of new ASD screenings done annually (diagnostic/rule-out autism visits)
 - iv. Total number of new ASD patients annually (new diagnoses)
 - b. Percentage of total ASD patient population in each of the government defined race categories
 - i. American Indian/Alaskan Native
 - ii. Native Hawaiian or other Pacific Islander
 - iii. Black or African-American (non-Hispanic)
 - iv. Black (Hispanic)
 - v. White (non-Hispanic)
 - vi. White (Hispanic)
 - vii. Asian
4. Payor Type Accepted
 - a. Percent of patients with private insurance
 - b. Percent of patients with public insurance
 - c. Percent of patients who self-pay

B. Biographical Sketch

The NIH Biosketch Format Page (not to exceed 4 pages) is required for the PI and each Co-PI. The form is available at <http://grants.nih.gov/grants/funding/phs398/phs398.html> or on the Autism Speaks grants system website. Combine and upload as a single PDF document.

C. Letter of Intent Narrative

The letter should be uploaded as a PDF and meet the following format guidelines:

- Total Page Limit: 4 pages, single-spaced
- Page setup: 11 point Arial, Times New Roman, or Palatino Linotype Font, 1" margins on all sides, 8 ½ X 11" paper (no A4)
- Numbering: All pages should be numbered sequentially in the bottom right corner.
- Headers: The RFA number should appear with the full name of the application's PRIMARY/LEAD Principal Investigator as shown (top right, justified margin).
Ex: Principal Investigator: LAST, First Middle Initial ATN-10-01

The document should be organized using the section headers indicated below.

1. STATEMENT OF INTENT (1-2 paragraphs)
Provide a statement indicating your interest in membership in the Autism Treatment Network. It should include a statement of your commitment to implementing the ATN model and provide assurances of institutional support for your application. Briefly explain why the institution is interested in the ATN model and explain its commitment to the ATN goals. Current ATN sites should highlight improvements in their clinic model made possible through ATN participation and state their goals for continuation. New sites should briefly describe how their current clinical and research activities are aligned with the goals of the ATN.
2. MODEL OF CARE (3-4 paragraphs)
Briefly describe your institution and your autism clinic, outlining how it meets the requirements of the ATN Model of Care as outlined in Section III.D of this RFA. If your institution supports more than one autism clinic, please provide a short description of each clinic including its purpose and target population.
 - a. Briefly describe how the ATN Assessment Battery can be integrated as standard of care.
 - b. Briefly describe how the core medical specialties designated in Section III.D will be integrated into the site's clinic flow. Describe the institution's ability to gain access to these medical specialists and build a collaborative clinical and research workgroup.
 - c. Briefly describe the current relationship with community primary care providers, outlining how you coordinate comprehensive care with the primary care provider community.
3. REGISTRY (1 paragraph)
Describe the site's commitment and capability to enroll children into the ATN Registry, providing evidence that the site can commit to enrolling 100 children per year into the ATN Registry and enter annual follow-up assessments for up to 3 years. Sites should briefly describe the site's existing data systems and data support staff. Indicate whether your site has an electronic health record and whether it supports or can support data export or interface with clinical registry systems.
4. COMMITMENT TO GUIDELINE DEVELOPMENT (1-2 paragraphs)
Describe the site's experience with developing evidence-based practice guidelines and supporting the development of clinical toolkits. Sites should address their capacity to participate in the piloting of guidelines. Current sites should briefly describe their involvement in guideline activities to date and outline their goals for the new grant cycle.
5. QUALITY IMPROVEMENT AND PATIENT SATISFACTION (1-2 paragraphs).
Describe the methods that your institution uses to measure patient satisfaction (e.g. survey, comment cards, etc.). Sites should describe experience with clinic-wide quality

improvement activities and explain how it relates to hospital-wide quality improvement activities.

6. PARTICIPATION IN ATN NETWORK ACTIVITIES (1 paragraph)

Provide assurances that the PI and other core personnel will be committed to participating in ATN core and subspecialty committees. Describe how accommodations will be made to ensure their participation. Include any relevant experience team members may have on multi-site collaborative committees (including current ATN committees).

7. RESEARCH ACTIVITIES (1-2 paragraphs)

Briefly describe the current clinical research activities in autism at the institution.

a. New sites: Describe how your current research projects are aligned with the ATN model.

b. Current sites: Describe your participation in ATN research activities to date and your plans for new research projects.

Optional: Briefly describe any interest and capacity you have to collect biomaterials and participate in a multi-site biorepository.

Section VI. Detailed Instructions for the Application

Full applications can be submitted only after a Letter of Intent has been approved by Autism Speaks. A checklist of required items is provided in Appendix 2.

All text documents should conform to the following:

Page setup:	1" margins on all sides; 8 ½ X 11" page size (no A4)
Font:	11 point Arial, Times New Roman, or Palatino Linotype font. A smaller font size may be used for figures, graphs, diagrams, charts, tables, figure legends, and footnotes, but this type must follow the font requirement and be readily legible.
Numbering:	All pages in this application should be numbered sequentially in the bottom right corner.
Headers:	The RFA number should appear with the full name of the study's PRIMARY/LEAD Principal Investigator as shown (top right, justified margin). Example: LAST, First Middle Initial ATN-10-01

A. Online Site Information (Full Application)

Once you have logged in to the grant system, you will have access to the online application **if your LOI was approved**. The first section consists of questions that you will need to enter online. The required information is outlined below. It is highly recommended that you gather and store the information in another format as a back-up.

1. Facilities and Resources
 - a. Clinical Spaces and Resources: labs/phlebotomists, pharmacy, sleep lab, MRI, EEG facilities
 - b. Distance between facilities
 - c. Number of personnel with ASD experience
2. Research Space and Resources: dedicated research labs and phlebotomists, pharmacy, EEG labs, MRI labs
 - a. Distance between facilities
 - b. Number of personnel with ASD experience
3. Identify participation in other multi-site research and training programs: ACE, STAART, CPEA, PPRU, RUPP, CTSA, SIMONS, ACTN, UCEDD, LEND, DBP Training program, IDDRC

4. Indicate if your site has interest in participating in future biorepository activities. If yes, provide information about your site's resources to support collection of biomaterials. (These resources are not required but will be considered a plus.)
 - a. -70C Freezer
 - b. Sample processing lab (materials and personnel to process and ship materials)
 - c. Centrifuge
 - d. Research phlebotomists including qualifications and experience
 - e. Types of materials the lab can process (blood, plasma, urine, stool)
5. Clinic and subspecialty wait times (by age if different) in weeks
 - a. Diagnostic visit
 - i. Medical visit (if separate)
 - ii. Psychological/behavioral assessments (if separate)
 - b. Sleep specialist
 - c. Pediatric GI
 - d. Pediatric Neurology
 - e. Medical Genetics/Metabolics (physician visit)
 - f. Speech-language pathology/OT
6. Does your site use electronic medical records? If yes, which system do you use?

B. Application Narrative

The narrative should not exceed 15 pages, single-spaced. This does NOT include table of contents, references or supporting materials such as budgets, budget justifications, or letters of support. This should be uploaded in the grant system as a PDF. Please organize your narrative according to the sections outlined below.

1. Introduction: Statement of Interest and Commitment to the ATN model
 - a. Provide a statement of intent indicating your interest in becoming a member of the Autism Treatment Network. Explain why your institution is interested in the ATN model and explain its commitment to the ATN goals.
 - b. Current Sites: Explain progress to date and goals for continuation. Describe how your participation in the ATN in the last two and half years (or more for legacy sites) has affected the functioning of your clinical site and improved overall care for patients, including those who are not being enrolled/were not enrolled in the ATN registry.
 - c. New Sites: Provide an overview of your current clinic model. Explain how your current autism activities align with and complement the goals of the ATN. Explain how your participation will expand and/or improve your clinic activities. In what ways will the activities of your program change as a result of your participation in the ATN? (Explain how participation will affect the *overall* functioning of your clinical and research programs. You will be asked to provide a more detailed description of day-to-day function in sections below).
 - d. Describe the kind of support the institution will provide to aid the implementation of the ATN model of care and the site's participation in the ATN network-wide activities. This should include a description of in-kind support, support of personnel, direct financial support, support of changes to clinical standard of care if needed, support of changes to the clinic data capture systems if needed, and a commitment to quality improvement. You should also identify in this section who will be writing the letter of institutional support. Specific instructions for the Letter of Support are included in Section VI.H.
2. Clinical Model:
 - a. Current Model
 - i. Describe your institution and the structure of your autism clinic, describing in detail how it meets the requirements of the ATN Model of Care as outlined in Section IIID.

- ii. Provide an overview of your annual patient volume including total ASD patients seen, total new ASD screenings (rule-out autism/diagnostic visits), and total new patients (new diagnoses). Provide a breakdown of the total ASD population into the government defined race categories (percentages): American Indian/Alaskan Native, Native Hawaiian or Pacific Islander, Black/African American (non-Hispanic), Black/African American (Hispanic), White (non-Hispanic), White (Hispanic), Asian.
- iii. Describe the acceptable payor types for your clinic, providing a breakdown of the percentage of patients with private or public insurance and the percentage who self-pay. If fee-for-service is a substantial part of your reimbursement, please explain how your clinic makes services available to families who might have difficulty paying.
- iv. If your institution supports more than one autism clinic, please provide a clear description of each clinic, including its purpose and target population and how these clinics coordinate intake and services.
- v. Include a description of your current approach to follow-up care and management of children.
- vi. Describe the current relationship with community primary care providers, outlining how you coordinate comprehensive care with the primary care provider community. Explain how you plan to incorporate your current mechanisms when implementing the ATN model.
- vii. Current ATN site members should describe any changes they have made to their clinic model throughout the first 2 ½ years of funding. Describe any planned changes to the site's current clinical model, if any, and provide a rationale for this change.

b. Integration of the ATN Model and Battery

- i. Describe how the ATN Assessment Battery is/will be integrated into the standard of care at the clinic.
- ii. Provide a detailed description of clinic flow, outlining how families are seen from intake to the completion of the entire diagnostic battery.
- iii. Include a description of how families will be/are invited and consented into the Registry. Include a description of who will be inviting the family, their experience with dealing with families for research, and a description of your consenting procedures. Describe who and how ATN families will be tracked including coordination with personnel who schedule the family visits. This should include a description of your site's patient tracking systems.
- iv. Describe how the core medical specialties will be/are integrated into the site's clinic flow. Describe the institution's ability to gain access to these medical specialists and build a collaborative clinical and research workgroup.
- v. Applicants must include a clinical flow diagram that illustrates the clinic flow for intake, referral and follow-up. This document will be uploaded separately, and is not included in the 15-page limit. See section VI. C.

3. Registry Support

- a. Describe the site's commitment and capacity to enroll children into the ATN Registry, providing evidence that the site can commit to enrolling 100 children per year. Currents sites should describe their enrollment activity to date, outlining any barriers to enrollment they have encountered and how these barriers were or will be overcome.
- b. Applicants should describe their capacity to enter data at baseline and for annual follow-up assessments for up to 3 years. Currents sites should describe their follow-up data collection activity to date, outlining any barriers they have encountered and how these barriers were overcome.

- c. Sites should describe previous experience with multi-site data collection activities, highlighting demonstrated success in meeting enrollment targets.
 - d. It is the intention of the ATN to move towards data capture methods that integrate ATN forms into the electronic medical record (EMR) system. Describe how your site could, if needed, integrate ATN forms/ATN data fields into your current EMR system. If your site does not have an EMR, describe any plans your institution has to implement the EMR, and how ATN data could be integrated into the system as it is rolled out.
 - e. Sites should also describe in detail the site's data systems and data support staff. Applicants should include an explanation of their processes and policies to ensure continuous support in the event of staff turn-over.
4. Personnel: Detailed outline of roles and responsibilities

Describe the respective roles and responsibilities among your proposed ATN team. Provide a description of the qualifications of each of the following key personnel. This should include not only a brief description of their background, but an explanation of their current position within the institution and brief description of their role on the ATN team. It is particularly important that you outline the specific roles and responsibilities of each of the Co-PIs. For example, who will be the primary individual with oversight over clinical activities? Who will take leadership with respect to participation in research activities? If an applicant is listing three Co-PIs, it is important that the responsibilities of each individual are clearly outlined. Current sites should include a description of an individual's previous/current responsibilities in network projects, including leadership roles he/she may have (e.g. committee chairs, training projects, guideline project leads). Brief descriptions of the expected roles and responsibilities are outlined below:

- a. **Principal Investigator (Site Director):** Responsible for overall oversight of ATN activities. This person is responsible for ensuring compliance with all network-wide activities including budgetary oversight, annual reporting and financial reporting. The PI is also responsible for ensuring that the site meets data enrollment targets, data quality, quality improvement and guideline obligations. This includes ensuring that the site is appropriately staffed for these activities and that the site is adequately represented on committees. The PI will represent the site on the Clinical Operations committee. It is preferable, but not required, that the PI be the individual with leadership over clinical activities. If the PI is providing research expertise, these qualifications should be described along with a rationale for why this individual is best suited to be the lead PI. If the PI will also serve as a subspecialty representative, this should be indicated and described here.
- b. **Co-Principal Investigator(s):** Responsible for supporting the PI in the oversight and management of ATN activities such as research or quality improvement. The Co-PI may have oversight over a particular aspect of ATN activities. The Co-PI represents the site on the Clinical Operations committee when the PI is unable to do so and may represent the site on committees which are relevant to their expertise. If the Co-PI will also serve as a subspecialty representative, this should be indicated and described here.
- c. **Pediatrics/Developmental Behavioral Pediatrics:** Within the ATN, the lead medical specialist with responsibility for coordinating a child's care is designated as a Lead Autism Specialist (LAS). This is typically a lead pediatrician/developmental pediatrician. In addition to being a lead point person for the coordination of care and the in-clinic implementation of the comprehensive care model, the Lead Autism Specialists participate in various subspecialty committees and consult with the Clinical Operations committee. The site should designate their Lead Autism Specialist and provide a description of his or her qualifications. In some clinics, the LAS may be a psychiatrist, or in some cases, a neurologist. In these cases, in addition to a description of the individual's qualifications, provide a description of how care is coordinated with pediatrics and why this subspecialty is more appropriate to take the lead for the care coordination at your clinic.

- d. **Other Subspecialty Representatives:** Subspecialty representatives have the following responsibilities: 1) Provide care to children seen in the autism clinic; 2) Provide leadership and training to other specialists at the site who may also be providing clinical care to ASD children; 3) Represent the site on their respective subspecialty committee; 4) Participate in network-wide quality-improvement and guideline development activities; 5) With other committee members, participate in the development of abstracts/manuscripts of Registry analyses in their respective areas of expertise. You should include the description and qualifications of the representative in each area below. You should list all areas.

If one of the PIs will also serve as a subspecialty representative, the description of his/her specific qualifications as a subspecialist can be included under the description for the role of PI/Co-PI. Be sure it is clearly indicated in the PI/Co-PI role description and that his/her specific qualifications are described. In the subspecialty section, you should list all areas, but you may indicate if a description can be seen under the PI/Co-PI. So for example, you could list: "Pediatric Sleep Medicine: See Co-PI description above".

- Genetics/Metabolics
- Pediatric Sleep Medicine
- Pediatric Gastroenterology
- Pediatric Neurology
- Behavioral Health (e.g. Psychology; Speech Language Pathology)

- e. **Quality Improvement:** Identify the member of your team who will be a point person for quality improvement activities and describe their relevant experience in quality improvement. This person leads and coordinates the team's activities while they test and implement the changes to the care, assures that tests of change are implemented, communicates closely with the data/site coordinators and assures that monthly data collection occurs and data entry is complete. This should be someone with delegated authority to ensure that quality improvement project targets are met. This person will also represent the site on the Quality Improvement Committee.
- f. **Site Coordinator:** The site coordinator is responsible for managing protocol implementation and data collection for the ATN Registry and guideline/quality improvement endeavors. The site coordinator collaborates with data personnel, clinicians, nursing staff, and front desk personnel to ensure that all information needed for the Registry is available and submitted in a timely manner. The site coordinator is responsible for coordinating patient tracking and enrollment, ensuring appropriate training of all relevant personnel on data management systems, reviewing data quality reports and ensuring the correction of any anomalies, and maintaining and monitoring regulatory documentation. For guideline/quality improvement activities, the site coordinator ensures that baseline and monthly data collection occurs for specific guidelines that are being piloted, compiles data and forwards to the project data coordinator, and completes reports. The individual should have experience with multi-site research/project management.
- g. **Data Coordinator/Manager:** The lead data coordinator is experienced with all aspects of data collection and works with the site coordinator to ensure the timely completion of data collection/entry and the submission of data quality reports.
- h. **Parent/Family Representatives:** To encourage more formal integration of family feedback in network activities, the ATN is establishing a Family Advisory Committee. Each site should identify two parents who will be involved in local ATN team meetings. Their purpose is to provide additional feedback and perspective to the site on the state of care and to get parental input on new clinical initiatives. The parent representatives will also participate in a network-wide Family Advisory Committee which will meet quarterly, including participation in the annual fall program meeting and three phone meetings. Two representatives are recommended to allow the parents flexibility with schedules while providing continuity for the committee.

- i. **Complete Personnel List:** In addition to this narrative text, you should complete the Personnel List and upload it according to the instructions in Section VI. D of this RFA. This may include clinicians or subspecialists who will provide clinical care to ASD children but will not be involved in network-wide activities.

5. **Commitment to Guideline Development**
Describe the site's experience with developing evidence-based practice guidelines and supporting toolkits. Sites should address their capacity and interest to participate in the piloting of guidelines. Current sites should include a description of their involvement in guideline activities to date, and outline their goals for the new grant cycle.

6. **Quality Improvement**
 - a. Describe your clinic's quality improvement plan, and provide examples of current or recent quality improvement projects that members of the proposed ATN team (PIs, medical specialists, nursing staff and/or coordinators) have been involved in.
 - b. Describe your team's capacity to meet the requirements of participating in network-wide quality improvement activities as outlined below:
 1. Commitment to transparency across the network in sharing performance data
 2. Commitment to identifying common and individual priorities for quality improvement
 3. Working collaboratively to continuously improve processes and outcomes of care for all children served.
 4. Activities may include the creation of site specific, multidisciplinary quality improvement teams and participation in network-wide quality improvement activities (including benchmarking and process improvement); collection of targeted data on children at the clinic who are not enrolled in the registry; frequent (typically monthly) reporting with both data and progress report information to track progress towards quality improvement aims.
 - c. Describe the methods that your institution uses to measure patient satisfaction and experience with care (e.g. survey, comment cards, etc.).

7. **Participation in Network Activities**
 - a. Provide assurances that the PI and other core personnel will be committed to participating in ATN Committees. Describe how accommodations will be made to ensure their participation. Include any relevant experience ATN team members may have on multi-site collaborative committees.
 - b. Current sites should describe their participation in network-wide committees to date, describe any barriers they may have faced to ensure representation on all committees, and how these barriers were or will be overcome in the next cycle.

8. **Clinical Resources**
 - a. Describe in detail the clinical resources outlined in your online form: labs, pharmacies, sleep labs, clinical MRI labs, and clinical EEG labs. You should include information about the size (square footage and number of rooms), number and experience of support personnel, and equipment (e.g. computer systems, type of MRI machines) for each of the resources provided in the list.

9. **Training Programs and Activities**
 - a. Describe your department's training programs for medical students and fellows including the number of students you train annually. Also describe your clinic's educational outreach programs for families and clinicians. Include the number of programs and the number of attendees annually.
 - b. Describe your participation, if any, in any national training programs such as DBP, LEND or UCEDD. Include the number of trainees hosted by your clinic annually.

10. **Research Activities**

While the ATN is primarily a clinical network, ATN members may participate in clinical research projects in support of the clinical mission of the ATN. All sites must have the capacity and expertise to participate in clinical research.

- a. Describe the current clinical research activities in autism at the institution.
 1. New sites: Describe how your current research projects are compatible with the ATN model.
 2. Current sites: Describe your participation in ATN research activities to date and your plans for new research projects.
- b. Research resources: Provide a description of your site's research resources as outlined in your online form: research labs/phlebotomy, sleep labs, MRI labs, and EEG labs. This should also include a description of your access to and the services provided by a General Clinical Research Center (GCRC) or Clinical Trials Unit, a Clinical and Translational Science Award Center (CTSA), and/or Intellectual and Developmental Disability Research Center (IDDRC) if applicable.

Optional: Indicate if your site has interest in future participation in a biorepository. Describe the capacity you have to collect biomaterials and participate in a multi-site biorepository. This should include a detailed description of your capacity to collect and ship biomaterials to a central location, capacity to store materials on-site, available personnel support for such activities, and description of the types of materials you can collect and process (e.g. spinning blood, preparing urine aliquots, processing stool).

C. Clinic Flow Diagram (1 page).

To supplement the text in the application narrative describing the clinic flow, all applicants must include a diagram outlining their clinic flow. This should be uploaded as a PDF.

D. Personnel List

To supplement the text in the application narrative, you must include a table of all participating personnel using the ATN Personnel List. This form can be found in the grant system on the application page. This form is a supplement to the 15-page narrative and is not counted in the narrative page count. Upload as a Word document.

Include all personnel with responsibility for the implementation of the ATN clinical activity and the percent dedicated to the ATN. This should include ALL personnel and not just personnel to be included on the budget. You should include the percent effort dedicated to ATN activity regardless of whether this activity will be covered under the budget. A description of specific personnel and activities covered by the budget will be included in the budget justification.

E. Budget

You must use the ATN budget form which will be available in the grant system.

F. Budget Justification

Provide a detailed and itemized budget by category (for each budget period). The budget justification is not considered part of the 15-page application. Restrictions and guidance on the use of funds are outlined in Section II of the RFA. The justification should not exceed 5 pages. Specific guidance for the budget justification will be available for download in the grant system.

G. Biosketches

Include a biosketch (Standard NIH Form required) for all PIs and key clinical personnel (MD, PhD, RN, NP), including the designated medical specialists. Upload PI's bio in the designated field in the online system. All others should be combined in one or two documents. The form is available at <http://grants.nih.gov/grants/funding/phs398/phs398.html> and in the grants system. Each biosketch should not exceed 4 pages.

H. Institutional Letter of Support

Applicants must provide a letter of support on letterhead from their institution acknowledging support for your participation in the ATN. The letter must come from the Dean of the Medical School, Vice-Chancellor or Department Chief. The letter must state the institution's support of the site's participation in the Autism Treatment Network, including the implementation of the ATN clinical model at the institution, support of the applicant clinic's participation in network-wide quality improvement efforts and guideline development, and a stated willingness to support the implementation of changes to the standard of care as needed. It is the intention of the ATN to move towards data capture methods that integrate ATN forms into the electronic medical record (EMR) system. This letter should also provide a statement to support integration of the ATN Registry activities with the institution's electronic medical record (EMR) system, at least in principle. If the site does not yet have an EMR, the statement should be supportive of including ATN Registry as part of the implementation of an EMR system at their institution. The letter should outline any specific support the hospital leadership will provide, such as financial support, personnel, material resources, or facilities/equipment. This should be uploaded in the grant system as a PDF.

I. IRB Acknowledgement

Include administrative acknowledgement (Institutional Notice or Letter) from the Human Subjects Institutional Review Board indicating the IRB's acknowledgement of the grant application. This is meant to demonstrate your planned IRB submission and target timeline for anticipated approvals. This should be uploaded in the grant system as a PDF.

J. Human Subjects Certification

Include proof that all identified key personnel have completed appropriate Human Subjects Ethics training and/or HIPAA training. Include copies of completion certificates for all identified key personnel. HIPAA certification can be obtained online through the Collaborative Institutional Training Initiative (CITI) – www.citiprogram.org.

K. References (if applicable)

Literature cited with complete literature citations including titles and all authors. Use the PubMed format for all citations.

L. Institutional Sign-Off/Submission

Once your application is uploaded, your Responsible Official will be required to complete the submission. **APPLICANTS CANNOT SUBMIT THEIR OWN APPLICATIONS.** They must be reviewed and submitted by the applicant's Responsible Official.

Section VII. Peer Reviews

Full applications will be reviewed by external members of the ATN Scientific Review Committee as well as external ad hoc reviewers with relevant expertise. Sites may be required to have an in-person site visit by ATN staff. Site visits will serve to confirm information about the site as outlined in the application. Site visit reports will be provided to reviewers for their consideration.

Applications will be reviewed using criteria in the following core areas:

- a. *Institutional Commitment:* Does the site have demonstrated commitment of the medical center and hospital leadership? Does the hospital leadership understand and support the integration of the ATN model and the ATN's mission of quality improvement? Will the site have the material, financial and facilities support to implement the ATN model?
- b. *Leadership:* Is the lead PI in an appropriate leadership position within the clinic to be able to institute changes in care models and clinic processes as needed? Do the PI and Co-PIs have appropriate experience and training? Do the PI and Co-PI have demonstrated experience coordinating multi-disciplinary clinical and/or research teams? Do the PI and Co-PIs have complementary expertise and experience?
- c. *Model of Care:* How well is the site's current clinical structure compatible with the ATN model of care? Is the site able to integrate the ATN battery and guidelines into the standard of care in their clinic? Will the site be able to make provisions for follow-up at the site or provide a mechanism to coordinate follow-up care with community physicians? Is the site able to provide access to all of the ATN specialties in a way that is reasonable and convenient for families?
- d. *Registry Support Capabilities:* Does the site have sufficient patient volume to enroll at least 100 children into the ATN Registry? Does the site have demonstrated experience enrolling families in clinical research or other registries? Does the site have a project coordinator and other support staff with appropriate experience to manage patient enrollment and patient tracking? Does the site have the appropriate support staff to maintain consistent data collection, data entry, and data quality?
- e. *Guideline Development:* Does the site have the capacity and willingness to pilot and implement ATN guidelines as part of their clinical practice? Does the site have appropriate staff to support data collection in support of guideline testing? Do the medical specialists have experience in the development of evidence-based guidelines?
- f. *Quality Improvement:* Does the site have the capacity and demonstrated commitment to participate in network-wide quality improvement endeavors? Does the site have demonstrated experience with quality improvement projects? Does the site have a key point-person with relevant experience to be the site lead on network-wide quality improvement projects? Is the site committed to transparency and the engagement of families in quality improvement?
- g. *Network Collaborations:* Has the applicant demonstrated willingness and commitment on the part of the PI, Co-PIs and key medical specialists to actively participate in ATN committees? Do the key personnel have experience participating in multi-site collaborations?
- h. *Training Activities:* Does the site have a well-established training program for medical students and fellows? Does the site participate in national training programs such as DBP, LEND or UCEDD? Does the site have well-established community education programs for professionals and parents?
- i. *Research Capacity:* Do the PI and/or Co-PIs have relevant, demonstrated experience in clinical research? Does the site have the capacity to support and participate in ATN relevant research projects? Does the institution have research support resources such as a GCRC or Clinical Trials Unit, or have resources through other multi-site research networks such as IDDRC, and CTSA?

Section VIII. Award Administration Information

A. Award Notification and Start

- a. The important dates are listed at the beginning of this document. Fund disbursements will not be made until contracts have been finalized and all IRB requirements are met.

- b. Human Subjects Certifications must be documented with a copy of an official letter of approval (or equivalent for non-US applicants), which identifies the Principal Investigator, project title and date of approval, and is signed by the Review Committee Chair or equivalent responsible institutional/government official. Prior certification for another project cannot be substituted.
 - c. IMPORTANT: IRB (or equivalent ethical) certification is not required to submit an application; however, IRB (or equivalent ethical) certification must be submitted as soon as possible following official notification of an award. Since the Autism Treatment Network sites follow a shared protocol, all sites use a standard protocol and consent template. These materials will be provided to sites upon notification of funding.
- B. Sharing Research Resources
- a. ATN members will have rights to access the shared Registry data for research. The sites must submit a formal request following procedures outlined in the Manual of Procedures and have their requests approved by the ATN Scientific Review Committee. Registry data may also be available to researchers outside of the ATN who are participating in a collaborative project with an existing ATN site, subject to SRC approval. Publications and presentations resulting from use of data from the ATN database must acknowledge the ATN, following requirements outlined in the ATN Manual of Procedures.
 - b. For more information on access to the ATN data and/or custom forms go to: http://www.autismspeaks.org/science/programs/atn/atn_physicians_researchers.php.
- C. Reporting
- a. At the end of each year, funded sites are required to submit a written progress report and an updated budget. A written final report is required at the end of the grant period. Release of funds for each additional year is contingent upon receipt of the progress report and the updated budget.
 - b. Sites have bi-yearly conference status calls with Autism Speaks ATN staff and staff from the Clinical Coordinating Center. Funded sites are subject to periodic in-person site visits by Autism Speaks ATN staff and staff from the Clinical Coordinating Center. Data management performance will be monitored on a regular basis for quality control and standards compliance.

Section IX. Contacts

Application Development and Budgets:

Nancy Jones, PhD: 323-297-4754 Email: njones@autismspeaks.org

Grants Administration/Online Application Questions:

Joan New, MBA: 609-228-7313 Email: jnew@autismspeaks.org

Appendix 1: Letter of Intent Checklist

Autism Speaks Grant System Log-in

Did you get your online grant system log-in? If not, see Section IV.A.

Online Site Information Form (Letter of Intent)

- *Personnel List*

See instructions in Section V.A.

NIH Biographical Sketch

See instructions in Section V.B.

Letter of Intent Narrative

See Section V. C for instructions.

Appendix 2: Full Application Checklist

Invitation To Submit A Full Application

Did you receive a notification with approval to submit a Full Application? If not, DO NOT PROCEED.

Responsible Official

Have you assigned a Responsible Official in the Autism Speaks grant system? If not, see section IV.C.

Online Site Information Form (Full Application):

Did you complete all the questions for the full application in the online grants system? If not, see instructions in section VI.A.

Application Narrative

See instructions in Section VI.B.

Clinic Flow Diagram

See instructions in Section VI.C.

Personnel List

See instructions in Section VI.D.

Budget

See instructions in Section VI.E.

Budget Justification

See instructions in Section VI.F.

Biosketches

See instructions in Section VI.G.

Institutional Letter of Support

See instructions in Section VI.H.

IRB Acknowledgement

See instructions in Section VI.I.

Human Subjects Certification

See instructions in Section VI.J.

References (If Applicable)

See instructions in Section VI.K.

Institutional Sign-Off/Submission

See instructions in Section VI.L.