Autism Speaks
Meixner Postdoctoral Fellowship in Translational Research
2016 Request for Applications

Letter of Intent due on or before: Tuesday, January 12, 2016, 8:00 p.m. (U.S. Eastern Time)
Letter of Intent decisions: Within 10 days of the Letter of Intent due date
Recommendations due on or before: Friday, March 11, 2016 by 8:00 pm (ET)
Application due on or before: Wednesday, March 16, 2016 by 8:00 pm (ET)

Other Important Dates (subject to change):
Peer review panels: Spring 2016
Notification: Summer 2016
Earliest Grant start date: early Fall 2016

The goal of this program is to support well-qualified postdoctoral scientists pursuing training in autism spectrum disorder (ASD) translational research. The program is open to applicants from public or private institutions doing preclinical or clinical research. Applicants are expected to detail a project that bridges basic laboratory research and behavioral or biomedical clinical research, and must include a training plan that includes mentoring in both basic and clinical research environments. Projects must have the fundamental translational research aim of accelerating the conversion of basic scientific discoveries into novel and more effective methods or products used to diagnose, prevent, or treat ASD. "Bench-to-bedside" approaches that delineate a path from preclinical models of ASD to well-defined patient populations, and "back-translational" projects that enrich the skill sets of behaviorists and clinicians through basic research on ASD biology and mechanisms of therapeutic intervention are equally encouraged. The results should have the potential to lead to or facilitate preclinical or clinical trials to improve outcomes for people with ASD.

A critical objective of the Fellowship in Translational Research is to foster frequent and impactful communication and collaboration among basic scientists, applied researchers, and clinicians across diverse research environments from academia to industry. To this end, trainees are required to have both a basic science mentor as well as a clinical mentor. The applicant should identify a primary mentor (i.e., the principal investigator with whom they directly carry out their research), and one or two secondary mentors that enable and expand their training and mentoring experiences into disciplines that complement their core research area and expertise and ensure meaningful exposure to preclinical and clinical research arenas. In addition, applicants must describe regularly-occurring local opportunities for two-way communication between preclinical and clinical researchers (e.g., monthly department meetings, Grand Rounds, multidisciplinary lab meetings). Scientific rigor, strength of mentorship, local environment and clear integration of preclinical and clinical elements in the training plan will be weighted heavily in the evaluation of applications.

Competitive fellowship applications will feature research projects that focus on the following areas of high interest to the science mission at Autism Speaks:

1. **Biomarker Discovery**: Identification and/or validation of biomarkers that demonstrate, for example, the potential to aide:
   a. Patient selection/stratification in clinical trials.
   b. Early diagnosis of patients.
c. Prediction or optimization of treatment response therapies in clinical trials.
d. And could include, but would not be limited to biochemical, genetic, imaging, physiological endpoints, and can include preclinical discovery research in animal model systems.

2. **Outcome Measure Development**: Development and/or validation of outcome measures that can be used to measure treatment response in clinical trials and support development of innovative therapies ranging from behavioral interventions to medicines or medical devices.

3. **Preclinical Target Validation**:
   a. Development of novel models systems (e.g. transgenic animal models, cell-based systems) that can be used as reagents to support rational selection of drug targets and evaluate experimental pharmacological agents.
   b. Development of novel assays that deliver preclinical endpoints to support rationalization of drug targets and evaluate experimental pharmacological agents.
   c. Projects aimed at using novel model systems and assays to characterize and validate candidate drug targets.

4. **Experimental Therapeutics**: Investigating the therapeutic potential of novel pharmacological, behavioral and technology-based applications that aim to address core symptoms or associated co-morbid conditions (e.g. psychiatric, neurological, somatic). Experimental approaches can include both exploratory clinical trials in humans and studies conducted in preclinical animal models relevant to autism. Autism Speaks views ASD as a whole body disorder, and applicants are encouraged to consider target biology and therapeutic hypotheses that address interactions between peripheral organ systems (eg gastrointestinal tract, immune system, sensory systems).

### Awards
Each Meixner Fellowship is awarded for a period of three years and includes both a competitive **stipend** (see below), and a **$10,000 annual allowance** intended to cover professional conference travel, research costs and supplies, and/or fringe benefits. Indirect costs are not allowed. Stipend ranges can be found below. The second and third year’s stipend will be raised to the next level, with the year 6 level being the maximum.

The **postdoctoral fellowship stipend** level will be determined by the number of years of postdoctoral experience at the time of the award to a **maximum of $64,000 per year**. Fellows are permitted to obtain additional awards or grants to cover research expenses only. Fellows may not hold any other award or grant that supplements their stipend.

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<tr>
<th>Years of Experience</th>
<th>Stipend Amount</th>
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<tr>
<td>0</td>
<td>42,800</td>
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<tr>
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<tr>
<td>6</td>
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### Eligibility
Applicants at U.S. and non-U.S. non-profit and for-profit institutions are eligible for this program. These entities include, but are not limited to, colleges, universities, hospitals, governmental entities, and for-profit research & development entities (eg biotechnology and pharmaceutical companies). Collaborative projects between public and private entities that diversify the training experience of the applicant are acceptable and encouraged. The site(s) where the applicant will conduct or participate in research training activities for the project must be clearly described in the individualized development plan (IDP;
described below). Projects involving for-profit entities require a letter from an authorized company representative declaring that the applicant’s work can and will be published, and that publication will not be delayed because of proprietary issues.

Postdoctoral Fellows: The candidate must hold an M.D., Ph.D. or equivalent terminal degree, and cannot have more than 5 years of postdoctoral experience at the commencement of the award. The selected postdoctoral fellow must spend at least 80% of his/her professional time engaged exclusively on the fellowship research activities for the duration of the award. The fellow may not simultaneously serve in an internship or residency, hold a tenure-track faculty appointment, or hold another named fellowship award during the support period. Postdoctoral training in the laboratory where the applicant received his/her graduate degree will not be reviewed.

Mentors: A primary mentor and 1-2 secondary mentors must be identified prior to applying for the translation research fellowship. **One mentor must be a basic science researcher, and one must be a clinician scientist.** All mentors must have Ph.D. and/or M.D. degrees and be scientific investigators with primary appointments at academic, public or private research institutions (e.g., tenured, tenure-track, or equivalent). They need to have a record of conducting high quality research, including a minimum of 1-2 peer-reviewed publications within the past 2 years in the field of the applicant’s research project. Prior mentoring experience and adjunct appointments will be considered and must be briefly described in the mentor’s Biosketch.

If the principal affiliation of the primary mentor is a for-profit institution, then the applicant is strongly encouraged to choose at least one secondary mentor whose chief appointment is at a non-profit college, university, hospital or other research institution including governmental entities. Statements of commitment and confidential letters of recommendation from all mentors must be included with the LOI and application respectively (see 2.f under “Completing the LOI” and 15 under “Complete the full application”). In addition, all mentors must sign the IDP that the Fellow candidate prepares (see section 5 below). **Multidisciplinary mentoring is required for this program, and the IDP will be evaluated for how well basic and clinical mentoring experiences are integrated to yield robust training in ASD translational research.**

Applications are strictly limited to **one per postdoctoral fellow or mentor per review cycle.** Multiple submissions will be returned.

**General Information**

All applications must be submitted through the web-based Autism Speaks Science Grants System, [https://science.grants.autismspeaks.org](https://science.grants.autismspeaks.org).

Please Note:

1. The Fellowship candidate must be the applicant. Go to [https://science.grants.autismspeaks.org](https://science.grants.autismspeaks.org) and register with your institutional email address (or log in if you have an ID). Complete your profile information. **Note:** You should enter the institution where the fellowship will take place, even if you are not located there at the time of LOI submission.
2. It is advisable to review the LOI page and then the Application page in the grant system well in advance of any submission date.
3. All uploaded documents should be 11 point Arial font with 1-inch margins all around (single spacing is acceptable) with the exception of NIH biosketches. Please do not have headers or footers in submitted documents. **Applications exceeding the specified document limits will not be reviewed.**
4. Preferred file type is PDF and must not be encrypted. Movie files are not acceptable.
5. Applications received after the deadline will not be accepted unless permission has been previously granted by the Autism Speaks Grants Office and then only due to rare and unavoidable circumstance. There are no exceptions to this rule. All decisions of Autism Speaks in regard to late submissions will be final. It is the applicant’s responsibility to plan around
holidays or any special circumstances at their institution.

6. 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 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 are to be completed and submitted by the applicant. Full applications can only be submitted by the RO.

7. There are no geographic restrictions on these applications. International applicants are encouraged.

**Resubmissions**
Candidates are allowed one resubmission of a previously denied Autism Speaks application. Resubmissions must meet the following requirements in order to be considered for review:

1. The Letter of Intent must indicate that the application is a resubmission and enter the prior ID# in the field provided. Also, it must include an Introduction describing how the resubmitted application will address the comments from the previous review, in the field provided (2500 characters, spaces included).
2. If the LOI is approved, the Introduction can be expanded (8000 characters, spaces incl.).
3. The new application research plan and other changed documents should indicate all substantive text changes. Changes should be easily identifiable using brackets, indents, or a distinguishable font. Do not underline or shade the changes. If significant portions of the original application research plan or other documents were deleted, the deletion should be explained in the Introduction. The application should also describe additional work completed since the original submission.

**Completing the LOI**
Log in and click Applications at the top of the profile page or ‘Go to Applications’ at the bottom. Choose ‘Start a new LOI or application’, then 'Meixner Translational Postdoctoral Fellowships 2016 from the Award Type drop down and finally “Start new letter of intent...” The Letter of Intent (LOI) includes two web pages.

1. **Basic Information Page includes:**
   a. Title: Enter less than 100 characters, spaces included
   b. Scientific Abstract. 1500 characters, spaces included. Provide a summary of the research project to be conducted and the skills that will be obtained by the trainee during the fellowship.
   c. If the application is a resubmission, select ‘Yes’ and the previous Autism Speaks ID number from the dropdown list of eligible IDs. The Introduction should explain how the resubmission will address the reviewers’ concerns or issues from the original application. (2500 characters, spaces included).
   d. Brain Tissue Sources, as applicable
   e. Expected Mentors and consultants (hint: start by entering the last name). LOIs without both primary and secondary mentors entered here will not be reviewed. **It is important to enter all participants you expect, even if they change later.**
   f. Choose the Responsible Official from your institution (see #6 under Application Submission on page 3). You must have an institutional email address to add a new official.
   g. Choose the keywords which describe this project.
   h. All this information will be available for changing/adding at the application stage.

2. **Letter of Intent Form includes:**
   a. How will the individual training plan integrate clinical and basic research training experiences and contribute to the fellow’s career development? Include training activities outside of the research (courses, rotations, conferences, etc) (up to 3000 characters, spaces included).
b. Biosketch for the fellow, NIH format not to exceed 5 pages.
c. Biosketch for the primary mentor, NIH format not to exceed 5 pages.
d. Biosketch for the secondary mentor, NIH format not to exceed 5 pages.
e. Biosketch for additional mentors, NIH format not to exceed 5 pages. (Optional)
f. A statement of commitment from each mentor explaining how they will provide resources essential to achieve the specific aims and career goals of the fellow. The mentor’s expertise, laboratory and/or clinical resources, and their joint ability to provide a rich translational training experience should be included. This should NOT be a letter of recommendation for the fellow. There will be an upload slot for each letter.
g. Projects involving for-profit entities require a letter from an authorized company representative declaring that the candidate’s work can and will be published, and that publication will not be delayed due to proprietary issues.

The LOI page is to be submitted by the applicant. Institutional officials are not required for this submission. The applicant will receive an email after Autism Speaks staff reviews the LOI. Candidates with approved LOIs will be able to move to the full application. **All LOI decisions are final and no comments will be available.**

**Completing the full application**

1. Once there is approval for the full application, entries on the Basic Information page can be edited. The rest of the entries listed here on are the application form (the 2nd page). Remember that the Introduction for Resubmissions will expand to 8000 characters in the application (on the Basic Information page).

2. **ORCID profiles** – Autism Speaks’ policy requires all applicants and mentors to obtain ORCID profiles. [Link to Help document](#).
   
   a. **Applicants** will not be able to work on their application until they have connected their ORCID profile to their Autism Speaks profile. Links in the Autism Speaks Science Grant system will make this step easy.

   b. **Mentors**: All mentors named on the application must also connect their ORCID profile to their Autism Speaks profile (it is not enough just to have an ORCID profile. See the [Help document](#)). **An application will not be reviewed until this is complete.** All mentors named on an application will receive an email with instructions however the applicant is encouraged to follow up with each individual. *(This is optional for consultants and non-mentor referees but is encouraged.)*

3. **Research Plan.** Not to exceed 8 pages. Project Narrative should include:
   
   a. Specific aims, background and significance/relevance to autism

   b. Preliminary data, including images or figures, if applicable. Note that any relevant publications, high resolution photographs or other supporting material can be uploaded under Exhibits.

   c. Experimental design, methodology and timeline for achievement of specific aims.

4. **Individualized Development Plan (IDP)** - Not to exceed 5 pages. The Translational Research fellowship is designed to encourage the most promising scientists to enter the field of ASD research with a clear plan for robust multidisciplinary translational research training. Candidates must describe an IDP that integrates the proposed clinical and basic research training experiences, mentoring relationships, and local educational opportunities (e.g., seminar series, department meetings), with an emphasis on how these components will enable the candidate to develop into a leading ASD researcher. The plan should describe the specific laboratory and clinical experiences that will be integrated into the fellowship, and the roles of each of the mentors (primary and all secondary).
The IDP must include significant experiences and mentoring in both laboratory and clinical environments. For fellows conducting bench or other laboratory research, clinical experiences may include, but are not limited to, involvement with a clinician in practice, shadowing a clinician or educator, and conducting screening or intake procedures. Alternatively, for fellows studying clinical or behavioral aspects of individuals with ASD, involvement in basic research settings must be described.

The training should add value above and beyond previous educational and research experiences. Describe the research training environment(s) and available resources (facilities, equipment, study populations and intellectual activities). The candidate must also include a personal statement addressing the value of the proposed fellowship experience and research training program for his or her preparation for a career as an independent, competitive scientist studying translational topics relevant to autism.

*** NOTE that all mentors must sign the IDP and that particular emphasis will be placed on how well it integrates the various training experiences.

5. **Responsible Conduct of Research Plan:** Outline all previous, current and future instruction. These plans may include coursework as well as individual and/or group training sessions with faculty, and should detail the duration and frequency of instruction. The mentor's role in promoting and ensuring the responsible conduct of research must be described. Please note, participating in online courses alone will not be considered sufficient instruction in the responsible conduct of research. In addition, while training in professional ethics, ethics in clinical research, or the ethical use of vertebrate animals is commendable and recommended, these topics are not sufficient to cover all aspects of responsible research conduct. See Appendix for list of topics. 3 pages max.

6. **Bibliography** with complete literature citations including titles and all authors.

7. **Budget** - The applicant must complete the online budget table showing how the research allowance will be spent. Allowable categories are Tuition Reimbursement, Fringe benefits, Research Supplies, Travel, Animal/Human Subjects Costs and Other (must be explained in the budget justification) Indirect costs are not allowed.

8. **Budget Justification.** Provide a detailed justification for each item on the budget. Include calculation(s) used. Uploaded document.

9. **Human Participants and/or Vertebrate Animals:** Applications that use human participants or vertebrate animals must address issues of protections. If no ethics approval is needed for the proposed research, please upload a memo to that effect. Note that ethical approvals from the applicant organization are required before an award will be made. These approvals do not serve in lieu of the information requested below.
   a. **HUMAN PARTICIPANTS** (defined as living individuals)
      i. Scientifically justify the involvement of human participants in the proposed research.
      ii. Describe in detail the plan for the involvement of human participants in the proposed research
      iii. Describe in details the potential risks to participants and measures to be taken to protect participants from those research risks.
      iv. For clinical trials, describe plans for data and safety monitoring, including the description of a data and safety monitoring board if necessary.
   b. **VERTEBRATE ANIMALS**
      i. Describe in detail the proposed use of the animals, including species, strains, ages, sex and number to be used
      ii. Justify the use of animals, choice of species and numbers to be used
iii. Provide information on the veterinary care of the animals
iv. Describe procedures for ensuring discomfort, distress, pain and injury is minimized. Please include the method of euthanasia and the reasons for its selection.

10. Consent forms (if applicable). If this project will be working with human subjects, upload the consent forms which will be used with the participants.

11. Letters of Collaboration (optional). Up to two one-page letters of collaboration may be submitted describing a collaborative arrangement.

12. Biographical sketches of all key personnel, not to exceed four pages per individual. Please use the NIH Biographical Sketch format. There will be individual upload slots for the fellow, primary and secondary mentors. All other files will need to be combined into one for upload –see the application page. Consultant biosketches are not required but strongly suggested. Biosketches should indicate all active and recently completed public and private funding, including source, total award amount, award duration (inclusive dates), and project title, both for the applicant and the primary mentor. Clearly explain the extent to which currently funded research projects will overlap, complement and/or contribute to the proposed research. Uploaded document.

13. Publications. Upload up to 2 publications which support the research plan. These do not have to be authored by the fellow or mentor. Publications are reviewed at the discretion of the reviewer.

14. Exhibits. Supplemental exhibits that support the Research Plan can be submitted. Multiple items should be combined into one file. Final file must be less than 4 MB. Items uploaded in this section will be reviewed at the discretion of the reviewer.

15. Three or Four Confidential Recommendations, including all mentors and at least one non-mentor referee (unrelated to the postdoctoral training). Each recommendation must be submitted in the online form in the Autism Speaks Science Grants System by each mentor/referee. Instructions for applicants and responsible officials can be downloaded HERE. Instructions for mentors/referees can be downloaded HERE. The reference letters should address the following information about the candidate:
   a.) commitment to a career focusing on translational research relevant to ASD
   b.) potential for conducting research
   c.) adequacy of scientific and academic background with specific reference to the candidate’s academic and research endeavors, including any publications, to date
   d.) evidence of originality
   e.) specific areas of further research training that would support the candidate in achieving a translational research focus in autism-related topics
   f.) any additional related comments that the referee may wish to provide

   It is the responsibility of the fellow to make sure each referee has the above instructions. These letters must be received on or before the deadline listed on page 1.

Submit the Application
When the application is complete, the applicant will click ‘Ready for RO Approval’ on the application form page. This can be done without all the recommendation letters submitted, however the Responsible Official will not be able to submit the application unless all letters are submitted. It is the responsibility of the applicant to contact their Responsible Official who must complete the submission. Applications must be submitted electronically using the Autism Speaks Science Grants System. Applications that are late, incomplete, exceed the document limitations, or do not adhere to the required format will not be reviewed. Applications that are faxed or emailed will also not be reviewed.
Autism Speaks reserves the right to return without review any fellowship application that in its judgment is not in compliance with its rules and procedures for application preparation and submission, is not responsive to its research training goals, or exceeds its funding limits or available resources. It is the responsibility of the applicant to ensure that the application is complete and conforms to the guidelines.

**Review Process and Evaluation Criteria**
Applications will be reviewed by independent peer review panels that will include active and experienced investigators in the research areas of the applications as well as our partners in the broader autism community. Fellowship applications will be reviewed on the merit of the training plan, the proposed research, the strength of the candidate and mentor, and the relevance to the goal of this fellowship (i.e., to facilitate the translation of biological discoveries into novel and more effective methods for diagnosis, treating, or preventing ASD).

**Notification and Announcements**
Applicants will be notified by e-mail after the funding decision process is complete. All grant awards shall be posted on the Autism Speaks website. The outcomes of each award will be posted after completion of the training project.

**Post Award**
The recipient of any grant from Autism Speaks must use the awarded funds as specified in the approved budget. Any funds not used in the above specified manner must be returned to Autism Speaks. Payment of the awards is contingent on receiving any institutional approvals (IRB or IACUC) that may be required for the research.

Fellowships will be paid annually and payment will be contingent upon completion and submission of the appropriate documents as explained in the grant agreement. A fellowship award cannot be transferred to another mentor, laboratory or sponsoring institution without prior written approval from Autism Speaks. Fellowships cannot be transferred to another fellow.

**Study Ethics**

*Human Participants and Vertebrate Animal 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, but can be officially amended to include the proposed project (identified by project title). **IMPORTANT:** IRB, IACUC or equivalent ethical certification are NOT required to submit an application; however, such ethical certification must be submitted as soon as possible following official notification of an award. Autism Speaks will NOT issue any form of funding until appropriate certifications are received.

*Projects using postmortem tissue* must provide documentation that the necessary tissue is or will be available at the research site at the time of the award. Applications without proper documentation will be returned without review.

**Contacts:**

**Application Development/Budget:**
Paul Wang, MD, Senior VP, Medical Research, 860-961-6022, paul.wang@autismspeaks.org

**Grants Administration/Online Application/Budget Questions:**
Joan New, MBA, Grants Manager, 609-228-7313, jnew@autismspeaks.org

**Recommendation Questions**
Naomi Jackenthal, Project Manager, 609-228-7326, naomi.jackenthal@autismspeaks.org
APPENDIX: Responsible Conduct of Research Plan

Outline all previous, current and future instruction. These plans may include coursework as well as individual and/or group training sessions with faculty, and should detail the duration and frequency of instruction. The mentor’s role in promoting and ensuring the responsible conduct of research must be described.

Please note, participating in online courses alone will not be considered sufficient instruction in the responsible conduct of research. In addition, while training in professional ethics, ethics in clinical research, or the ethical use of vertebrate animals is commendable and recommended, these topics are not sufficient to cover all aspects of responsible research conduct.

Responsible Conduct of Research includes most of the professional activities that are related to a research career and specifically encompasses the following nine areas:

a. Conflict of interest – personal, professional and financial
b. Policies regarding human subjects, live vertebrate animal subjects in research, and safe laboratory practices
c. Sponsor/fellow responsibilities and relationships
d. Collaborative research including collaborations with industry
e. Peer review, including confidentiality and disclosure of participation by anyone not directly assigned to the materials under review
f. Data acquisition and laboratory tools; data management, sharing and ownership
g. Research misconduct and policies for handling misconduct
h. Responsible authorship and publication, with topics including fabrication, falsification and plagiarism
i. The scientist as a responsible member of society, contemporary ethical issues in biomedical research and the environmental and societal impacts of scientific research

Document requirements: Word or PDF, 3 pages max, Arial 11 font, 1 inch margins, single space is acceptable.