SPARK Clinical Site Network
Request for Applications (RFA)

BACKGROUND & RATIONALE
The overall goal of SPARK is to recruit, engage and retain a research community of 50,000 individuals with autism spectrum disorders (ASD), along with their family members in the United States. This research cohort includes children and adults with ASD, who span the full spectrum of autism and includes individuals of all socio-demographic backgrounds. In the months since the initiative launched in April of 2016, SPARK has recruited over 30,000 participants, including 5,000 “trios,” which are families comprised of a child with ASD and both of his/her biological parents.

SPARK participants contribute medical and behavioral information online, collect and mail in saliva samples for DNA analysis, and are invited to participate in future research studies. In addition, the SPARK community will provide researchers with an efficient way to identify eligible participants for their research studies. Individuals who enroll in SPARK will receive up to $50 in gift cards as well as access to the following: 1) an opportunity to receive aggregate and individual behavioral results from their participation, 2) an opportunity to receive individual genetic results that are pertinent to their autism diagnosis, and 3) interactive webinars and recent articles regarding autism research. Visit www.SPARKforAutism.org for additional information about the study as well as the clinical sites that are currently supported.

In order to effectively build the SPARK community, we will recruit participants through clinical sites, including past and current research registries, and through partnerships with advocacy organizations and service providers. Participant data will be shared back to the clinical site or registry that referred them to enrich the local research efforts of the clinical site or research registry.

SPARK is an initiative of the Simons Foundation Autism Research Initiative (SFARI). SFARI’s goals include supporting research that will lead to better ways to treat and to improve the lives of individuals with ASD. Some of SFARI’s major goals are: to develop more reliable quantitative, objective outcome measures for ASD clinical trials; to develop biomarkers to stratify ASD patients and demonstrate efficacy of treatments; to develop partnerships with individuals with ASD and clinical providers to promote ASD research; and to enable and evaluate new, potential therapies and supports for individuals with ASD.

SCOPE OF RFA
SFARI will support a network of U.S.-based clinical sites for the purposes of recruiting individuals and families affected by ASD to participate in SPARK. Annual support to each clinical site will include the following allowable costs:
• Site director(s) salary — we will allow up to 10 percent effort for a PI or PI(s), but the total amount of funding requested, including indirect costs, must not exceed $150,000 per year;
• Site coordinator(s) salary — a site can have more than two coordinators, but we strongly encourage the arrangement of one full-time site coordinator or two part-time site coordinators at 50 percent effort each;
• Funds for conducting community outreach to catchment area (excludes direct payment to participants);
• Funds for recruitment and retention materials and supplies, such as tablets to assist families with online registration; and
• If applicable, funds to support return of genetic and behavioral results.

Selected sites will receive funding on an annual basis for up to three years. The maximum amount of funding awarded per year is $150,000 including 20 percent indirect costs (see SFARI policies).

Sites will be required to submit quarterly progress reports to help determine eligibility for renewal. Annual renewal of funding is based on the site’s performance in meeting recruitment targets of individuals and families who qualify for the study, entering relevant clinical data and promoting retention of the cohort.

The award start date is April 1, 2017, and sites will be expected to begin enrollment no later than June 1, 2017.

**SPECIFIC WORK TO BE ACCOMPLISHED**
Selected sites will be responsible for the following:

**Recruitment planning**
• Obtain local IRB approval to waive oversight to a centralized IRB. **If your IRB is unable to cede oversight to a central IRB, your site cannot participate in SPARK. SPARK’s central IRB is Western IRB.**
• Develop a recruitment strategy in alignment with central IRB protocol, inclusive of identifying existing research cohorts available for re-contact; local patient databases with email/phone contacts; and community partners working with individuals with ASD and their family members.

**Outreach & Recruitment**
• Conduct remote and in-person recruitment (defined as enrolling eligible participants through the submission of saliva samples) of individuals with ASD and their family members who visit the clinical site
• Recruit individuals with ASD and their family members via re-contact of local research participants and patients who have agreed to be re-contacted for future research opportunities
• Reach out to community groups and organizations that serve individuals with autism and their family members to enhance recruitment by speaking at local events, hosting a booth at a walk, contacting local advocacy groups, etc.
• Following up with participants with regards to return of genetic results and completion of new survey modules

Data entry
• Abstract and enter assessment scores from participant medical records or transferring data from a local database into the study portal. We expect IRBs to accept the standard HIPAA language in the centralized consent.
• Upload medical records of enrolled participants into the study portal

Tracking progress over time
• Track the number of individuals with ASD and their family members recruited per month
• Participate in monthly site coordinator conference calls to share information about recruitment efforts and receive updates on overall project status

ELIGIBILITY AND COLLABORATION
All applicants and key collaborators must hold a Ph.D., M.D. or equivalent degree and have a faculty position or the equivalent at a college, university, medical school or other research institute. Applications may be submitted by domestic nonprofit organizations; public and private institutions, such as colleges, universities, hospitals, laboratories, units of state and local government; and eligible agencies of the federal government. Applications may also be submitted by for-profit companies, in which case the funds provided for the grant are to be used only for charitable purposes toward research related to autism spectrum disorders. There are no citizenship or national residence requirements for applicants.

If the proposal includes investigators at more than one site, all investigators should have demonstrated prior success in similar collaborations.

IMPORTANT DEADLINES
Application deadline January 13, 2017
Notification date February 1, 2017
Start date April 1, 2017

SPARK will hold an informational conference call on Thursday, December 15, 2016. Please email Alex Stephens at astephens@simonsfoundation.org if you are interested in participating.

INSTRUCTIONS FOR SUBMISSION
The deadline for receipt of applications is January 13, 2017. Applications must be completed electronically and submitted using forms provided at http://proposalcentral.altum.com/. Please log in as an applicant, go to the GRANT OPPORTUNITIES tab, scroll to CLINICAL RESEARCH ASSOCIATES and click APPLY NOW for the SPARK Clinical Site Network Request for Applications program.
Full applications require the following components to be included (for more details, see the “Instructions” document, available for download in the DOWNLOAD TEMPLATES AND INSTRUCTIONS section of proposalCENTRAL):

A. Completed **Application Form**:
   a. Patient population and enrollment estimates across catchment area
   b. Waiver of oversight to central IRB
   c. Recruitment objectives
   d. Site experience
   e. Other site capabilities

B. **Recruitment plan**: Description of how site plans to recruit participants and partner with local organizations for outreach/recruitment (1 page)

C. **Activity timeline**: Month-to-month description of activities with clear start and end dates (1 page)

D. **Budget**: Should include cost estimates for components listed above; budgets are limited to up to $150,000 per year for up to three years, inclusive of 20% indirect costs.

E. **Budget justification** (one page)

F. **Biographical sketch** of PI, site coordinator and all clinical staff who evaluate children/assign diagnosis

G. **Research environment and resources**: Investigators should demonstrate access to appropriate resources for high-capacity data collection and analysis, although we will work with awarded investigators to provide additional informatics support as needed.

H. **Optional**: **Letters of support** from community organizations (up to three)

**EVALUATION PROCESSE**
SFARI will evaluate proposals based on information provided in the application and associated documents. External reviewers will most likely not be used. SFARI scientific staff will make final funding decisions, and notification of award is expected by February 1, 2017. Preferred applicant sites will be able to demonstrate the following:

- Extensive history of participating in/leading research studies of individuals with ASD
- Proven track record of successful recruitment for large-scale research projects
- Extensive history of providing clinical care to individuals with ASD
- Large number of individuals with ASD seen per year
- Large number of individuals with ASD available for re-contact
- Large catchment population
- Diverse catchment population

The aforementioned criteria are by no means exhaustive.

**CONTACT INFORMATION**
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