

July 1, 2009

Dear Colleague,

Because of your background and experience in the field of fluency and fluency disorders, we are sending you the RFP below. In summary, the RFP solicits interested qualified institutions and/or individuals to conduct an efficacy or basic science research study regarding the use of SpeechEasy®, an electronic in-the-ear fluency device, or its associated technology.

SpeechEasy was patented in October 1999 by the Department of Communication Sciences & Disorders at East Carolina University, and introduced to the public in June 2001 by the Janus Development Group. Since then, over 7000 devices have been sold in the United States.

In November 2007, Janus assembled an independent research review panel to assist with the development of additional RFPs, the evaluation of submitted proposals, and the selection of final grant recipients. The first RFP was created and publicized in July of last year, with Dr. Ken Logan from the University of Florida selected as the award recipient. Dr. Logan is currently initiating this research, entitled the "Effect of Concurrent Behavioral Fluency Therapy Upon Stuttering Treatment Outcomes in Speakers who Use the SpeechEasy Device".

Janus Development Group is now seeking to sponsor additional research, as suggested in the attached RFP. No one on the panel has any interest in or connection to SpeechEasy, Janus Development, or East Carolina University.

If you are interested in applying for this grant, please follow the instructions given below.

Sincerely,

Janus Research Review Panel

# Request for Proposals: Studies of the SpeechEasy® Device

## Introduction

Janus Development Group, Inc. invites grant applications to conduct basic and applied research studies into mechanisms of action and outcome effectiveness of the SpeechEasy device, and the technology that the device employs.

For this funding cycle, proposals will be given priority if they address basic research on responses to perturbed auditory feedback (e.g., DAF, FAF, combined signals) in children between the ages of 8 and 18, including but not limited to speech fluency and its underlying acoustic and/or kinematic features.

Other types of proposals may be submitted, but will be given lower priority for funding. Any such proposals must address one of the following:

- Comparisons of two or more groups of children and/or adolescents who stutter who receive traditional treatment versus a group whose treatment program includes the SpeechEasy. Age, stuttering severity, and gender need to be controlled.
- A series of single participant studies of the conditions noted above, in which the participants serve as their own controls.

We will consider study proposals that satisfy one or more of the following requirements:

- Examine for statistically significant differences between treatment/listening conditions.
- If an intervention design is used, describe changes in stuttering (including SLDs and other form types) and related attitudes and feelings following two (or more) treatment conditions.
- Small pilot studies on topics relevant to SpeechEasy technology or clinical use, if the design can be adopted by other investigators to yield significant results.

We anticipate that each award will be for a period of one or two years in an amount not to exceed \$50,000. Funding will be granted for the following categories:

- Principal Investigator time/effort
- Research Assistants (faculty and students)
- Payment of participants
- Audiovisual recording media (e.g., CDs, DVDs, audio/video tapes)
- Essential equipment (full justification and specified costs required)
- Data analysis costs
- Research supplies, services and related expenses

Funding will **not** be granted for any of the following expenses:

- Laboratory space rental or refurbishment
- Travel costs for investigators
- Indirect costs (including, but not limited to those that supply tuition, health insurance, etc.)

Budgets are reviewable and subject to modification by the review panel.

## **Eligibility**

Applicants must provide a Curriculum Vitae that indicates appropriate training in research design and statistical analysis. Graduate students working under the supervision of a faculty researcher may apply, but must also submit their academic advisor's CV as part of the application. Applications will not be accepted from persons who are associated with Janus Development Group or their families, or from members of the Review Panel.

## **Application Process**

### **Letter of Intent**

The applicant must first submit a Letter of Intent via email to Janus, Inc. that includes the following information:

- a) A concise description of the proposed project including: specific aims, methods and expected results.
- b) A clear explanation of the project's relevance to one or more goals of this RFP and potential basic or applied research significance.
- c) Names, titles and institutional affiliations of active collaborators/co-investigators in addition to the PI (excludes consultants, postdoctoral fellows, students and technicians)

*The Letter of Intent cannot exceed 2 pages (approximately 1000 words).* Janus, Inc. and its Research Review Panel will invite Full Proposals only from previously submitted Letters of Intent. Full Proposals must be consistent with aims and methods articulated in the Letter of Intent.

### **Proposal Preparation**

Full Proposals invited after review of Letters of Intent should be written in 11 point Arial font with 1-inch margins all around.

A typical pilot study proposal will include the following sections:

- A) **Abstract** (maximum 500 words), which must describe the project goal(s) and/or hypothesis, specific aims, research methods, expected results and basic research or clinical relevance.
- B) **Research Plan** (maximum 10 single-spaced pages not including separately uploaded figures and tables, if they will add to the clarity and content of the application):
  1. Hypothesis and Specific Aims
  2. Background and Significance
  3. Preliminary studies conducted by the applicant, if available (optional)
  4. Research Plan and Methods
- C) **Bibliography** with complete literature citations including titles and all authors
- D) **Annual Budget**: Investigator salaries and benefits, and tuition reimbursement for any research team member are **not** allowed. *See pp.1-2 for allowable budget items.*
- E) **Budget justification**: Justify personnel costs, project-dedicated resources, services and equipment and any unusually costly expenses or travel
- F) **Description of relevant facilities** and necessary on-site and off-site resources
- G) **Biographical Sketches of Investigator(s)**: We prefer NIH format, not to exceed 3 pages each
- H) **Protection of Human Research Subjects**: All proposed research must undergo review by an Institutional Review Board (IRB) for protection of human subjects. Documentation of IRB approval, along with copies of the protocol, Consent Form, and Minor Assent Form, if used, must be provided before awards can be made. Proposals must include the name, contact information, and federal-wide assurance (FWA) number of the IRB used, along with the proposed protocol title and if available, the protocol number assigned by the IRB. Applicants are encouraged to begin the IRB review process early, as the approval process can take some time.
- I) **Letter of endorsements**

## **Post- Award Considerations**

Annual Reports will be expected from all funded individuals/groups receiving support for greater than one year. A Termination/Completion Report will be expected from all funded projects, to include full description of findings and dissemination plans.

Janus Development Group, Inc. will provide the following “in-kind” support to successful research applications:

- SpeechEasy devices in preferred configuration(s)
- Demonstration kit with necessary accessories
- Software programming that emulates the functions of SpeechEasy for laboratory-based research proposals
- Onsite training for research personnel consisting of overall orientation and hands-on use of all equipment

## **Submission of Letters of Intent and Proposals**

Letters of Intent and Full Proposals are to be submitted by email to:

Janus Development Group  
Attn: Alan Newton  
112 Staton Rd.  
Greenville, NC 27834  
252-551-9042  
[anewton@janusdevelopment.com](mailto:anewton@janusdevelopment.com)

Attachments should be in Word (PC platform). Proposal submission will be confirmed by email to the applicant.

For **2009, submission dates are:**

Letter of Intent Due: **August 31, 2009**  
Invitation to Submit Proposal: **October 16, 2009**  
Full Proposal Due: **January 8, 2010**

**IMPORTANT!** Letters of Intent and Full Proposals will NOT BE ACCEPTED after their due dates unless prior written permission is obtained. Janus reserves the right to return without review materials not considered to be in compliance with the information provided in this RFP.

Review Process and Evaluation Criteria:

- Proposals will be reviewed by the Janus Research Review Panel.

Pilot study proposals will be evaluated using the following criteria:

- Innovation
- Relevance and potential significance
- Approach: Are the experimental design, methods and analyses likely to achieve the desired aim(s) of the pilot study, including the development of essential preliminary data and/or the establishment of “proof of concept” for a larger study? Have potential problems and alternative approaches been considered?
- Investigators’ qualifications: Do the investigators have the appropriate training and experience to conduct the pilot study? Have they demonstrated satisfactory productivity in terms of peer reviewed publications in the area of the proposed research? Have necessary collaborations been established and documented with letters of agreement?
- Environment: Is the institutional support sufficient? Do the investigators have access to necessary research resources either on site or off site? Has access to necessary special research equipment or facilities been appropriately documented with letters of agreement?

**Please direct questions about this proposal to Alan Newton by telephone at (252) 551-9042 or by email at: [anewton@janusdevelopment.com](mailto:anewton@janusdevelopment.com)**