CARILION CLINIC

August 20, 2015

Andre Muelenaer, MD
Pediatric Pulmonology and Allergy

RE: Using Wireless Accelerometers to Quantify General Movements

Dear Dr. Muelenaer:

I am pleased to inform you that the Institutional Review Board (IRB) of Carilion Clinic has reviewed the personnel changes and status change described on the Change/Update Form, received 7/6/15, in an Expedited manner. The study is Reactivated. Also, Ben Cragun and Okmin Pyon are added to the research team and have met IRB requirements. Individual Investigator Agreements were executed for them as well as Ashley Taylor, who was already on the research team. The change does not alter the scientific validity of the study or the assessment of the risks and benefits of the study. The personnel changes and Reactivation have been approved.

I would like to remind you that the principal investigator must provide the Institutional Review Board with a report summarizing the status of the project every year. The principal investigator should submit a continuing review application thirty (30) days prior to the expiration date, providing a summary of the project to date and requesting permission for continuation of the original project. It is also your responsibility to report to the IRB serious adverse events or unanticipated problems, as outlined in the IRB Guidelines, which can be attributed to this study within seven (7) business days of notification. In addition, copies of reports from Data Monitoring Committees or auditing/monitoring reports from a sponsor must also be sent to the IRB Research Compliance Officer within seven (7) business days. Any changes to the research study must receive IRB approval before those changes can be implemented unless subject safety is directly affected. The IRB must be notified immediately about subject safety issues. The IRB must be notified within seven (7) business days if and when a project is discontinued.

The Institutional Review Board of Carilion Clinic would like to thank you for allowing us the opportunity to review this protocol. We look forward to learning of your results.

Sincerely,

Charles A. Hite, MA, CIP
Human Protections Administrator, Carilion Clinic IRB

cc: file

Institutional Review Board
2001 Crystal Spring Avenue, SW, Suite 202 Roanoke, VA 24014-2465 P.O. Box 13367 Roanoke, VA 24033-3367
Phone: 540-853-0728 **Fax:** 540-985-5323

Carilion Clinic Institutional Review Board

RESEARCH CHANGE / UPDATE FORM

RECEIVED
JUL - 6 2015

Date Completing Form: 07-02-2015

Complete Title of Study: Using Wireless Accelerometers to Quantify General Movements

Principal Investigator Name: Dr. Andre A. Muelenaer, Jr, MD **Address**: 102 Highland Ave SE, Suite 203 **Phone**: 540 985 9810 **E-mail**: aamuelenaer@carilionclinic.org

Fax: 540 985 4018 **Inter-office address**: Pediatric Pulmonology and Allergy

Other Investigator (s): Alfred L. Wicks, PhD **Study Coordinator and Other Research Team Member(s)**: Ashley Taylor

Original Board Approval Date: 12-04-12

Number of Local Subjects Enrolled: 12

Is the study Open or Closed to Enrollment? closed

What is Being Changed? (choose all that apply)

Date of Change: 07-02-2015

Type of Change:

- ☐ **Protocol (Submit entire updated protocol with all changes highlighted or in track changes. If the IRB application serves as your protocol, submit the application with changes highlighted. Submit the revised original without highlights, as well.)**
- ☐ **Consent Form (Submit an electronic version of the new consent form with all changes highlighted or in track changes. Submit the revised original without highlights, as well.)**

Check All Changes that Apply:

- ☐ Inclusion/Exclusion Criteria; specify:
- ☐ Procedure; specify:
- ☐ Medication; specify:
- ☐ Diagnostic Tests (i.e., blood draws, radiology exams, etc.); specify:
- ☐ Identification of New Risks; specify:
- ☐ Number of Visits; specify:
- ☐ Length of Study; specify:
- ☒ Personnel/Contact Information; specify: add: Ben Creegan + Okmin Ryan
- ☐ Clarifications or Typographical Errors; specify:
- ☐ Other; specify: Ashley Taylor did Inv Agree but already on team (Investigator Agreements)

Tracking Number if Applicable: (Example: Protocol Revision #4, 1/1/09, and/or Consent Revision #3, 1/1/09)

Other Changes? (choose all that apply)

- ☒ **Study Status Change:**
  - ☐ **Temporary Closure to Accrual of Subjects:** Effective Date: Reason:
  - ☐ **Suspension:** Effective Date: Reason:

X **Reactivation:** Effective Date: **07-02-2015**

☐ **Permanent Closure to Accrual of Subjects:** Effective Date:

- ☐ Subjects receiving research interventions
- ☐ Treatment complete, subjects in follow-up
- ☐ Data analysis
- ☐ Other; specify:

☐ **Recruitment Materials Change (attach new documents and those currently in use with changes highlighted for comparison): Date Describe Change**

X **Local Personnel Change (attach copy of 1572 if applicable)**

Specify Person's Full Name, Credentials and Role in Project:

A. Okmin Pyon. Candidate for Master of Science in Mechanical Engineering. Ms. Pyon will assist in collection of data and perform data analysis.

B. Benjamin Cragun, MD. Dr. Cragun previously participated in this protocol and will again perform analysis of recorded videos in order to identify infant movements of interest in this study.

☐ **Investigator's Brochure (attach copy of updated Investigator's Brochure)**

Investigator's Brochure Version #: Date:

☐ **Other Change or Submittal:**

Specify:

Signature of Principal Investigator

07-02-2015
Date