

## **INSTITUTIONAL REVIEW BOARD STATEMENT**

**Title:** Impaired Swallowing Mechanics of Post-Radiation Treatment Head and Neck Cancer Patients: a Retrospective Videofluoroscopic Study

**Running Title:** Post rtHNC Swallowing Mechanics

**Authors:** William G. Pearson, Jr., Ph.D., Alisa A. Davidoff, MS, CCC-SLP, Zachary M. Smith, MS, CF-SLP, Dorothy E. Adams, MS, CCC-SLP, Susan E. Langmore, PhD, CCC-SLP, BCS-S.

**Institutional review board statement:**

The study was reviewed and approved by the Boston University School of Medicine Institutional Review Board. **(PLEASE SEE ATTACHED SIGNED LETTER on Pages 2-3 of this pdf)**



Boston University  
Medical Center



Office of the Institutional  
Review Board  
560 Harrison Ave, Suite 300  
Boston, Massachusetts  
02118-2526  
Tel: 617-638-7207  
Fax: 617-638-7234

**Title of Study:** Functional Importance of Hyolaryngeal Elevation in Swallowing  
**Protocol Number:** H-31123

**RE:** New Protocol  
**Review Type:** Exempt  
**Action:** Categorical Exemption

**Date of Action:** July 25, 2011  
**Date Revisions Were Accepted:** July 25, 2011

**Funding Source:** Not Funded  
**Award #:** n/a

**Protocol Version #:** 1.0

Dear William Pearson,

A qualified member of the BUMC Institutional Review Board (IRB) staff has reviewed the above referenced protocol and has determined that it does not require further review by the BUMC IRB because this study was determined to be EXEMPT in accordance with 45 CFR 46.101.

This study qualifies as Exempt under the following categories:

(4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

**Protocol Specific Determinations**

**-Approve HIPAA Waiver of Authorization**

**Requirements:**

1. Please note that Zachary Smith may not conduct any activities related to this protocol until proof of Human Subject's Protection in Training is obtained by the Office of the IRB.
2. Please note that Exempt Category 4 research does not allow for complete dates (month/day/year) to be included in

the data set **only partial dates (i.e. month/year) may be included in this Exempt Category 4 data set.**

This approval corresponds with the version of the protocol indicated above.

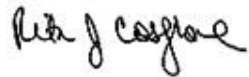
All determinations regarding this project have been made based on the information submitted by the investigator. Any modifications to the research plan (including any changes in funding) must be submitted to the IRB for review and approval prior to initiation, and may change the IRB's determination.

The IRB office does not require continuing review for studies that have been designated as EXEMPT under the categorical exemptions.

It is the responsibility of the PI to ensure that any HIPAA requirements have been met prior to initiating this study. Validated HIPAA forms may be found within INSPIRE II under Study Documents.

It is also the responsibility of the PI to ensure that all required institutional approvals have been obtained prior to initiating any protocol related activities.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Rita J. Cosgrove".

Signature applied by Rita Cosgrove on 07/25/2011 03:55:46 PM EDT

IRB Board Member