INFORMED CONSENT 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.

Informed consent statement:
The Boston University School of Medicine Institutional Review Board approved a waiver of informed consent due to the use of existing clinical data collected in a manner that subjects cannot be identified, and the added risk of the invasion of privacy and possible compromise of confidentiality introduced by obtaining consent.

See attached below: The approval of HIPPA Waiver of authorization refers to the waiver of the requirement to obtain consent from participants. HIPAA is the (US) Federal Health Insurance Portability and Accountability Act that protects the confidentiality and security of healthcare information for health care patients in the US.

Boston University Medical Center

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Office of the Institutional Review Board
560 Harrison Ave, Suite 300
Boston, Massachusetts
02118-2526
Tel: 617-638-7207
Fax: 617-638-7284

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.

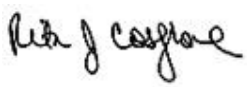
All determinations regarding this project have been made based on the information submitted by the investigator. Any modifications to the research plan (including any changes in funding) must be submitted to the IRB for review and approval prior to initiation, and may change the IRB's determination.

The IRB office does not requiring 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 INSPIR 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,



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

IRB Board Member