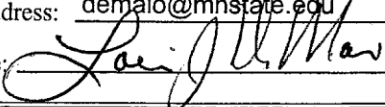


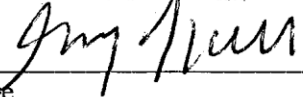
- Institutional Review Board (submit completed form to Graduate Studies Office)
 Departmental Review Committee (submit completed form to Committee Chair)

Human Research Approval Form

Principal Investigator (must be MSUM faculty):		
Name: <u>Louis J. De Maio</u>	Address where you want to receive IRB correspondence:	
Telephone: <u>4643</u>	<u>Speech/Language/Hearing Sciences</u>	
E-mail address: <u>demaio@mnstate.edu</u>	<u>Library Porch</u>	
Signature: 	Date: <u>September 3, 2007</u>	
Co-Investigator: Attach separate sheet if more than two	Co-Investigator: Attach separate sheet if more than two	
Name: _____	Name: _____	
<input type="checkbox"/> Faculty <input type="checkbox"/> Graduate Student <input type="checkbox"/> Undergraduate Student	<input type="checkbox"/> Faculty <input type="checkbox"/> Graduate Student <input type="checkbox"/> Undergraduate Student	
If graduate student, is this research part of your final project/thesis?	If graduate student, is this research part of your final project/thesis?	
<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Telephone: _____	Telephone: _____	
E-mail address: _____	E-mail address: _____	
Signature: _____	Signature: _____	
Title of study: <u>SLHS 491 Research Applications: Senior Projects</u>		
Date submitted: <u>9/3/08</u>	Project starting date: <u>9/29/08</u>	Project ending date: <u>12/8/08</u>
Request: <input checked="" type="checkbox"/> Exempt Status (complete <i>Request for Exempt Status</i>) Submit original and 1 photocopy		
<input type="checkbox"/> Expedited Review (include reasons below) Submit original and 1 photocopy		
<input type="checkbox"/> Full Review Submit original and 10 photocopies		
Reason for requesting Expedited Review: <div style="border: 1px solid black; height: 20px; width: 100%;"></div>		

Institutional Review Board Recommendation:

- Exempt Status Approval: Yes No Revise and Resubmit (see attached)
 Expedited Review Approval: Yes No Revise and Resubmit (see attached)
 Full Review Approval: Yes No Revise and Resubmit (see attached)

IRB Chair's Signature:  Date: 9/10/08

This form and complete instructions are available online at: <http://www.mnstate.edu/irb>

Clear Form

**Institutional Review Board
Request for Exempt Status**



- Institutional Review Board (submit completed form to Graduate Studies Office)
 Departmental Review Committee (submit completed form to Committee Chair)

Name of Principal Investigator	Louis J. De Maio
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Title of study	SLHS 491 Research Applications: Senior Projects
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1. How are the subjects at no more than minimal risk?	The procedures for the studies were all commonly established and accepted educational practices. All of the data were collected from clinical activities at the MSUM Speech, Language, and Hearing Clinic as part of the typical procedures used in providing services to clients.
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2. How will informed consent be obtained? (Include copy of informed consent form or implied consent letter for surveys)	The present studies are using data from studies previously approved by the IRB in which informed consent was obtained.
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3. How will assent be obtained when minors or other vulnerable populations are used?	Three of the studies involve analyzing data from mothers of children with language impairments; therefore, no method of assent was necessary. The Auditory Processing Disorder study required that the children tested had to complete the assessment procedure in order to receive a differential diagnosis which was the reason they came to the clinic for testing. Only the data from the children that completed the assessment was used in these studies.
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4. How will confidentiality be maintained?	The identities of the subjects are anonymous. Students will only have access to numerical data sheets. Identities of the subjects were destroyed years ago.
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...continued on page 2

Request for Exempt Status, continued

5. Select the type of research that applies to your study and **provide a brief explanation below***



Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. **This is the only area of exemption that may apply to minors, whereby the researcher is the minor's teacher, instructor, therapist, etc.**

Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior that is not exempt under paragraph 2 of this section, if (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

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.

Research and demonstration projects which are conducted by or subject to the approval of federal department or agency heads, and which are designed to study, evaluate, or otherwise examine: (i) public benefits or services programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

Taste and food quality evaluation and consumer acceptance studies, (1) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environment contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

* brief explanation ...

There will be four different types of studies conducted by the students in this class. All of these studies will be using data from other studies that were approved by the IRB under category 1 of exemption. The students will only have access to numerical data recorded on spreadsheets or data sheets, and they will not know the identities of any of the subjects.

Louis J. De Maio

IRB Proposal: *SLHS 491 Research Applications: Senior Research Projects*

September 8, 2008

Summary

Students in SLHS 491 are expected to conduct research on existing clinical data. This is a requirement for their degrees in Speech/Language/Hearing Sciences. The data for these studies come from original studies that received IRB approval more than three years ago under category 1 of exemption. Informed consent was obtained at this time.

There will be four different types of studies conducted in SLHS 491 this year. Three types of studies will involve investigations of mothers' communication patterns before and after going through the Parent-Child Communication Program (De Maio, 2000). The last type of study will involve examining a specific screening tool for auditory processing disorders.

Subject identities are completely anonymous. The students will only receive numerical data. The data has been recorded on spreadsheets or data sheets that do not contain any identifying information.