GUIDELINES FOR

BST 698/699

BIOSTATISTICS MAJOR PAPER/THESIS

Produced and Distributed by: University of Miami
Division of Biostatistics
Department of Public Health Sciences
Graduate Programs
BIOSTATISTICS PROJECT GUIDELINES

PURPOSE
The purpose of the Biostatistics Major Paper/Thesis (BST 698/699) is for the student to demonstrate competency as a Master of the Biostatistical Sciences. The student may decide to pursue either the Major Paper Option (enrolls in BST 698 for 3 credits) or the Master’s Thesis Option (enrolls in both 698 and 699 for a total of 6 credits, 3 each). In the Major Paper option, the student can choose to analyze a substantial applied problem/project or a student may focus on an evaluation of a collection of related methods in a branch of statistics.

MAJOR PAPER OPTION:

Guidance for a substantial applied problem: A substantial applied problem would involve a research question in which the student would document the properties of the data involved, create and document an appropriate analysis strategy, implement the data analysis and clearly describe and illustrate the results. The research question and analysis involved need to be of sufficient complexity to document the student’s analytic thinking ability with respect to statistical practice and would generally require some research of various potential statistical approaches to the problem. The paper would then review and explain the decision-making process (and potentially the preliminary analyses) the student took in determining the appropriate analysis strategy.

Guidance for evaluation of related methods: The student is expected to explain a collection of related methods in some branch of statistics, use several of them to solve a motivated problem, explaining and contrasting the results. This process could use existing data, simulation or both.

THESIS OPTION:

In a Thesis a student would be expected to explain a collection of related methods in some branch of statistics, motivate and develop a non-trivial variation on one of them, elucidate its properties and use it to solve a problem of interest, and compare the new method to some established methods.

GETTING STARTED
Students must first review the requirements (handbook) for completing the BST 698/699 project (available online at the Graduate Programs website). Students then meet with the Capstone Manager to discuss their project topic ideas and potential faculty that could serve as major paper/thesis committee members. At this time, based on the student’s topic area, the Capstone Manager will assign a Capstone Faculty Advisor.
CHOOSING A TOPIC
After meeting with the Capstone Manager and receiving an assigned Capstone Faculty Advisor, the student is required to meet with their Capstone Advisor. The major paper/thesis topic is developed by the student in consultation with their assigned Capstone Advisor. A determination must also be made regarding the necessity of IRB approval.

ESTABLISHING A MAJOR PAPER/THESIS COMMITTEE
Students are required to have a minimum of three faculty committee members. The minimum 3 members will include a first reader, a second reader and the Biostatistics Program Director (Dr. Hemant Ishwaran). The assigned Capstone Faculty Advisor will serve as either the first or second reader, depending on their expertise in the selected topic area. Please see Appendix B for a complete list of Division and Department faculty.

1. First Reader: Must have an appointment in the Division of Biostatistics, Department of PHS and is involved in the day-to-day supervision of the project. This individual should have expertise in the subject area. If not, the Second Reader is then required to have expertise in the subject area. The first reader will approve the final manuscript and complete the oral presentation assessment form (See Appendix E).

2. Second Reader: Also works closely with the student on all phases of the project, but may not necessarily be involved in day-to-day supervision. This individual does not have to be a Division/DPHS faculty member.

3. Biostatistics Program Director: Approves proposal and attends presentation if the thesis option is chosen. Answers more involved logistical questions regarding the project.

PROPOSAL/CONTRACT
A proposal/contract must be completed and signed prior to the time of registering for BST698/699. It must state the title, purpose of the project and problem to be addressed, hypothesis formulated, background information that will be used, methods of data collection or description of the existing data, description of data analysis procedures, and the IRB approval process.
The student is responsible for determining and obtaining the signatures on the left side of the contract from their First Reader, Second Reader, and Biostatistics Program Director prior to registering for the project. Please see Appendix C for the BST Student/Faculty Contract.

**DATA REQUIREMENTS**
The major paper of a substantial applied question typically will have a data component and include statistical analysis of that data. Any project that includes the use of data on human subjects must address Institutional Review Board Requirements.

**INSTITUTIONAL REVIEW BOARD APPROVAL**
All projects that involve data collected on human subjects must obtain Institutional Review Board (IRB) approval prior to initiation of the project. Since this process can be quite cumbersome and may take up to six weeks, it is recommended that students collaborate with faculty members who have existing research projects with IRB approval. If an existing IRB approval is used, a copy of the approval form must be attached to the BST 698/699 contract and to the final manuscript. In some cases analyses on totally de-identified data can be exempted from IRB oversight, however the IRB must determine this. In this case, a copy of the IRB determination of exemption would need to be included.

Students who will require IRB approval can obtain the necessary forms and guidelines from the Human Subjects Office (243-3327). Keep in mind that for the purposes of the IRB Behavioral Sciences Subcommittee, the principle investigator of the project MUST be a UM faculty member. Students are to be listed as collaborators, even if the research is a thesis or dissertation. The faculty member named will be held responsible for the content of the protocol.

**COMPLETION OF BST 698/699 REQUIREMENTS**
Review of the project requires completion of a manuscript detailing study findings. Students choosing the thesis option and therefore also enrolling in BST 699 must also prepare an oral presentation detailing study findings. Detailed format requirements for the paper are provided in Appendix D.

An oral presentation of findings, which lasts one hour, should utilize a similar format and conclude with a question and answer session with the project committee. This question and answer session may cover material relevant to the whole biostatistics curriculum, not just the project. The student must coordinate with the Capstone Manager and committee members on time, date, and location of the oral presentation.
Once the project is complete, the student is responsible for obtaining final signatures on the right side of the contract from the First Reader, Second Reader and Biostatistics Program Director. At that time, a final grade of S (satisfactory) or U (unsatisfactory) will be awarded. In some cases, the committee may request changes to the project prior to assigning a grade.

**DEADLINES**
The following deadlines must be adhered to when completing the Biostatistics Major Paper or Thesis:

1. The final draft of the Biostatistics Major Paper or Thesis must be submitted to the administrative office and to all committee members **at least three weeks prior to the end of the semester and at least one week prior to the scheduled oral presentation**. At that time, the student must contact the Capstone Manager to reserve a room for the presentation. It is the student's responsibility to schedule the oral presentation at a time which is suitable to the committee members.

2. The oral presentation of the project must be completed no later than **1 week prior to the official end of the semester**.

3. The final version of the project is to be submitted to the Capstone Manager on the day of the oral presentation, unless revisions are requested by the committee.

**INCOMPLETES**
It is optimal for students to complete their Biostatistics Major Paper or Thesis in the same semester in which they register for BST 698/699. In certain circumstances this may not be possible, and the student may request an "I" (Incomplete). All incompletes must be completed within one (1) year.
APPENDICIES

TABLE OF CONTENTS

The appendices include all required forms, including contract, program competencies, formatting guidelines and supporting material to help guide the student, Faculty Supervisor and Capstone Faculty Advisor through completion of the Major Paper/Thesis project. Documents must be signed and submitted electronically to the Capstone Manager. Each document must be saved with the student’s last name followed by an underscore and the document name. (Ex. Doe_F.E. Proposal or Doe_C.P. Final Thesis).

Appendix A: MS BST Program Competencies (Page 7)
Appendix B: List of Biostatistics Division and Department (Page 8)
Appendix C: BST Student/Faculty Contract (Pages 9-10)
Appendix D: Formatting Guidelines for Major Paper/Thesis (Pages 11-12)
Appendix E: Oral Presentation Assessment Form (Page 13)
APPENDIX A

Program Competencies
Master of Science in Biostatistics

Upon completion of the Master of Science in Biostatistics (MS) degree, all graduates will be able to:

• Describe the core disciplines of public health and how they apply to improving population health
• Apply epidemiologic methods to the measurement and study of population health and the prevention of infectious and chronic disease
• Describe concepts in probability theory, random variation and commonly used statistical distributions
• Have a solid grounding in intermediate mathematical statistics
• Develop sample size and power calculations for different study designs including those from clinical trials
• Perform a variety of statistical analyses (estimation and inference) including ANOVA, multiple regression, generalized linear modeling, multivariate analysis, survival analysis, design of experiments, various new techniques from statistical learning theory, analyze longitudinal data and spatial data
• Interpret results from above statistical analyses to draw relevant conclusions from data
• Communicate effectively by producing summary reports, statistical analysis sections of papers, graphical summaries and tabular summaries of the data
• Develop oral presentations of statistical analyses for primarily public health and medical professionals
• Develop a high level of competency in statistical programming both with R and SAS for both managing and analyzing data
• Recognize potential ethical issues and implement the concepts of ethical conduct of research
APPENDIX B

FACULTY LIST

Division of Biostatistics Faculty:

Kristopher Arheart, EdD
Daniel Feaster, PhD
Orlando Gomez-Marin, PhD
Yongtao, Guan, PhD
Hemant Ishwaran, PhD
Tulay Koru-Sengul, PhD
Sherri Messinger, PhD
Victor Pestien, PhD
Subramanian Ramakrishnan, PhD
Sunil Rao, PhD
Isildinha Reis, DrPH

Department of Public Health Sciences Faculty:

John Beier, ScD
Scott Brown, PhD
Margaret Byrne, PhD
Noella Dietz, PhD
WayWay Hlaing, MBBS, PhD
Viviana Horigian, MD
Jennifer Hu, PhD
Lanetta Jordan, MD, MPH
Erin Kobetz-Kerman, PhD, MPH
Roderick King, MD, MPH
Julie Kornfeld, PhD, MPH
Naresh Kumar, PhD
David J. Lee, PhD
Howard Liddle, EdD
Kathryn McCollister, PhD
Clyde B. McCoy, PhD
Hilda Pantin, PhD
Tatiana Perrino, PsyD
Guillermo Prado, PhD
Cindi Rowe, PhD
Seth Schwartz, PhD
Mark Stoutenberg, PhD, MSPH
Jose Szapocznik, PhD
**APPENDIX C**

**BST Student/Faculty Contract**

Name: _______________________________            Student ID#:  _________________

**BST 698/699 – BIOSTATISTICS MAJOR PAPER/THESIS**

**STUDENT/FACULTY CONTRACT**

This contract is to be completed and submitted to the Graduate Programs Office prior to registering for BSFT 698/699.

**Credit Allocation**: Students register for BSFT 698/699 - Biostatistics Project (1-6 credits) after completing all prerequisite work. Students may register over several semesters. The final grades earned will be S (satisfactory) or U (unsatisfactory).

**Course Description**: The purpose of the biostatistics project is to allow students to demonstrate competency in the assessment, development and implementation of appropriate biostatistical methods to address a public health research question.

**NOTE**: BST 698/699 IS THE REQUIRED CULMINATING “CAPSTONE” EXPERIENCE FOR THE MS IN BIOSTATISTICS DEGREE.

**Term Beginning**: _____________ Oral presentation completed by: ______________________

Final draft of the public health project must be distributed to all committee members and the EPH Graduate Programs office at least one week prior to the oral presentation:

Student Signature: ___________________________ Date: ___________________________

Using the format on the attached sheet, state the title, introduction, background, and methods you will be using

<table>
<thead>
<tr>
<th>Approved by:</th>
<th>Completion certified by:</th>
</tr>
</thead>
<tbody>
<tr>
<td>____________</td>
<td>________________________</td>
</tr>
<tr>
<td>First Reader’s signature</td>
<td>Date</td>
</tr>
<tr>
<td>Second Reader’s signature</td>
<td>Date</td>
</tr>
<tr>
<td>Director’s signature</td>
<td>Date</td>
</tr>
</tbody>
</table>

**Final Grade Earned:** _____
COMPLETE THE FOLLOWING SECTIONS  
ATTACH ADDITIONAL SHEET IF NECESSARY

PROJECT TITLE

INTRODUCTION:
• Purpose of the project:

• Hypothesis(es) you formulated:

• An explanation of why this project is substantial and of sufficient analytic complexity to require substantial assessment and work to determine the appropriate analysis strategy

BACKGROUND:
• List background information available to you:

METHODS:
• List measures you will use:

• Describe the data that will be used:

• Describe your role in the project:

• Describe your data analysis procedures:

• Will human subjects be used: _____Yes _____No  
  If yes, attach IRB approval forms
APPENDIX D

BST Major Paper/Thesis Formatting Guidelines

The paper MUST BE TYPED DOUBLE-SPACED on 8 1/2" x 11" heavy duty white paper. Type on only one side of the paper. Allow generous margins on each page - at least 1 1/2" at the left side and 1" for the top, bottom, and right side. Number pages (in Arabic) consecutively, beginning with the title page. Type the page number in the upper right-hand corner of each page. The paper should include title page, abstract, text, acknowledgements, references, tables, and legends with each manuscript component beginning on a new page. Students must submit a signed electronic copy to the capstone manager; students should keep copies of everything submitted.

TITLE PAGE
The title page should carry all of the following centered on the page 1) the title of the article, which should be concise (but informative) and descriptive; 2) first name, middle initial, and last name of the author; 3) course numbers (BST 698/699); 4) month and year in which the paper is completed; 5) signature and printed name of the capstone faculty advisor and 6) the statement, "Submitted to the Graduate Programs in Public Health in partial fulfillment of the requirements for the degree of Master of Science in Biostatistics" placed at the foot of the title page.

ABSTRACT
The abstract must be 150 to 250 words summarizing the project's essential points. It should be understood without access to the entire project.

TEXT
The text is usually divided into sections with the headings: Introduction, Background, Methods, Results, and Discussion.

Introduction: State the purpose of the project and the hypothesis you have formulated. Summarize the rationale for the study or observation.

Background: This includes a brief summary of the available background information

Methods: Describe your selection of the observational or experimental subjects clearly. Identify the methods, apparatus, and procedures in sufficient detail to allow other workers to reproduce the results. Give references to established methods, including statistical methods; provide references and brief descriptions for methods that have been published but are not well known; describe new or modified methods, and evaluate their limitations. Identify all drugs and chemicals used. Describe the methods used to acquire the data for the project.
Results: Present your results in logical sequence in the text, tables, and illustrations. Do not repeat in the text all the data in the tables, illustrations or both; emphasize or summarize only important observations.

Discussion: Emphasize the new and important aspects of the study and the conclusions that follow from them. Do not repeat data or material from previous sections. Include the implications of the findings and their limitations, including implications for future research. Relate observations to other relevant studies. Link the conclusions with the goals of the study but avoid statements and conclusions not completely supported by your data. Recommendations, when appropriate, may be included.

ACKNOWLEDGEMENTS
Keep acknowledgements to a minimum. Acknowledge only persons who have contributed to the scientific content or provided technical support.

REFERENCES
References must be numbered and cited consecutively in the text. At the end of the paper, references must be listed on a separate page in the numerical order in which they are first cited in the text. Personal communications and unpublished data should not be included in the list of references. References 1) must include names of the first six authors; when there are seven or more; list the first three, then "et al"; 2) complete title of the article cited; 3) name of journal abbreviated according to Index Medicus; 4) year of publication, but omitting day or month of issue; 5) volume number; and 6) inclusive page numbers.

TABLES
Tables should be self-explanatory and should supplement, not duplicate, the text. Each table must be typed, double-spaced, on a separate page. Each table must have a title and be numbered consecutively and cited in the text.

FIGURES
Figures consist of all material that cannot be set in type, such as photographs, line drawings, graphs, charts, and tracings. Omit all figures that do not increase understanding or that repeat information given in the text. Each figure should be numbered consecutively and cited in the text. Each illustration must have a descriptive legend which should not exceed 40 words in length. Legends should be typewritten, double-spaced, on 8 1/2 x 11" paper and identified by number.
# APPENDIX E

## Oral Presentation Assessment Form

<table>
<thead>
<tr>
<th>Program:</th>
<th>Date:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Student Name:</td>
<td>Student's UM ID:</td>
</tr>
<tr>
<td>Rating of (circle one):</td>
<td>Master's Thesis</td>
</tr>
<tr>
<td><strong>Knowledge of the discipline</strong></td>
<td>1 = Unacceptable</td>
</tr>
<tr>
<td>Error(s) in exposition of the field and/or omission of key source(s)</td>
<td>Minor errors, omissions, and/or lack of synthesis</td>
</tr>
<tr>
<td><strong>Appropriate methodology</strong></td>
<td>1 = Unacceptable</td>
</tr>
<tr>
<td>Error(s) in methodology selection and/or use</td>
<td>Minor methodological errors and/or omissions</td>
</tr>
<tr>
<td><strong>Application of knowledge and methodology to original research topic</strong></td>
<td>1 = Unacceptable</td>
</tr>
<tr>
<td>Discipline and methodology not referenced/supplied well</td>
<td>Some links to discipline and methodology but not clearly integrated with research</td>
</tr>
<tr>
<td><strong>Critical thinking</strong></td>
<td>1 = Unacceptable</td>
</tr>
<tr>
<td>Misunderstanding and/or coherent analysis and synthesis</td>
<td>Reasoning sometimes confused, simplistic, and/or not clearly explained</td>
</tr>
<tr>
<td><strong>Effective written communication</strong></td>
<td>1 = Unacceptable</td>
</tr>
<tr>
<td>Writing generally unclear, with consistent errors and/or poor organization</td>
<td>Writing sometimes unclear with weak organization and/or grammatical errors</td>
</tr>
<tr>
<td><strong>Effective oral communication</strong></td>
<td>1 = Unacceptable</td>
</tr>
<tr>
<td>Presentation generally unclear, with poor organization and/or marked by distracting mannerisms or language</td>
<td>Presentation sometimes unclear, with weak organization, and/or some distracting mannerisms or language</td>
</tr>
<tr>
<td>Overall quality (not necessarily average of earlier ratings)</td>
<td>Unacceptable</td>
</tr>
</tbody>
</table>

**Comments:**