

Meharry Medical College
School of Graduate Studies and Research



Guide to Thesis Preparation
Master of Science in Public Health

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PREFACE

Students of the Master of Science in Public Health program at Meharry Medical College must exhibit confirmation of a high degree of erudition, competence in scholarly exposition, and the capacity to select, systematize, and apply knowledge learned during matriculation through a thesis. This guideline handbook provides a detailed overview of the thesis process from onset to commencement. This manual is comprised of examples of best practices concerning format standards that must be met before the student receives final approval by the Division of Public Health Practice (DHPH).

ACKNOWLEDGEMENTS

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INTRODUCTION

PURPOSE OF THE GUIDE

This guide is designed to be a basic source of information which will aid in the preparation of the MSPH thesis. Its purpose is to outline the steps involved and establish the technical parameters of the thesis, such as the quality of paper, number of copies to be submitted, margins, and the sequence of pages within the document. Since most graduate students will publish during and after their graduate education, it is also logical to encourage the use of leading professional publications to help establish specific formatting conventions. Students are encouraged to use publications such as journals and textbooks within their field to help them in establishing heading format, bibliographic form, use of numbers, and other conventions that are discipline oriented. The application of this theory is not simple, however. It becomes necessary for students to understand the various elements of a manuscript and general publication formatting requirements in academic publishing. Although knowledge and use of publication formatting is essential, the regulations established by this *Guide* always takes precedence over any other style manuals for final submission of the thesis.

Style handbooks such as the *MLA Handbook for writers of Research papers*, *Publication Manual of the American Psychological Association*, *A Manual for Writers*, and/or *The Chicago Manual of Style* should also be used as resources for basic style and grammar. In contrast, previously accepted theses should never be used as the final guide to style. Examples taken from other theses may be out of context or may be incorrect. The existence of a particular style or usage in a previously thesis does not establish a precedent for its continuation.

Meharry Medical College, by accepting a thesis and awarding the degree, places its academic reputation on the line. While the technical quality and content of the thesis is evaluated by the student's Committee on Instruction (THESIS COMMITTEE), the Office of the SOGSR imposes format requirements to ensure an appropriate academic appearance of the manuscript.

STUDENT INTEGRITY

In part, and very importantly, conferral of a degree implies personal integrity and ability to perform within the framework of scholarly methods. There are four areas in which graduate students should be particularly cautious: [1] proper acknowledgment of cited works; [2] use of internet links; [3] use of copyrighted material; and [4] proper reporting of work subject to federal compliance regulations (e.g., use of human subjects, animal care, radiation, legend drugs, recombinant DNA, or the handling of hazardous materials).

1. Proper Acknowledgment of Cited Works

Students must take care not to plagiarize. "Plagiarism is using the intellectual property or product of someone else without giving proper credit." Any material taken from another source must be fully acknowledged, and in no case should one present another person's work as one's own. Extreme caution should be exercised by students involved in collaborative research to avoid questions of plagiarism. If in doubt, students should check with their major professor and the SOGSR about the project. Plagiarism will be investigated when suspected and appropriate action taken if necessary.

2. The Use of Internet Links (Embedding)

Students may use links in their document as long as they do not give the impression that the material to which it is linked is their own. Students should ask permission to include a link to external material. If they do not receive permission, they may provide the address (URL) without providing the link. Students should use discretion in including links because the content of websites frequently changes, unlike published journal articles or books. Students should not link

to material that is integral to their thesis/dissertation. They should instead seek permission to include that material in their thesis/dissertation.

3. The Use of Copyrighted Material

The law governing copyright infringement is based on a principle called “fair use.” If copyrighted material is used in a limited way, permission to quote usually need not be sought. Also, “no permission is needed to quote works in the public domain... such as publications of the United States Government” (*Chicago Manual of Style*, 2003, pg. 119). Unlike other material, a standardized test, figure, table or other graphical representation should not be reprinted in the thesis/dissertation unless permission has been granted. The source must be cited under the table/figure if permission is granted (*APA*, 2001, pg. 174). If extensive material from a copyrighted work is to be used, such that the rights of the copyright owner may be violated, permission from the owner must be obtained. Even when permission is not needed, make sure to cite the owner’s works fully. In determining the extent of a written work that may be quoted without permission, the student should consider the proportion of the material to be quoted in relation to the substance of the entire work. According to *The Chicago Manual of Style* (2003):

Use of any literary work in its entirety—a poem, an essay, a chapter of a book—is hardly ever acceptable. Use of less than the whole will be judged by whether the second author appears to be taking a free ride on the first author’s labor....Proportion is more important than the absolute length of a quotation; to quote five hundred words from an essay of five thousand is likely to be more serious than from a work of fifty thousand (pg. 136).

The publisher usually has the authority to grant permission to quote excerpts from the copyrighted work or can refer requests to the copyright owner or designated representative. The copyright owner may charge for permission to quote. Permissions should be credited on the acknowledgments page, and the source should appear in the list of references/bibliography section.

4. Reporting of Work Subject to Compliance Regulations

Compliance with federal regulations governing the use of human subjects, animal care, radiation, legend drugs, recombinant DNA, or the handling of hazardous materials in research is monitored by a number of federal agencies. Because of these regulations, research compliance is another area of importance to graduate students and to the conduct of their research. Every student is required to verify that he or she has complied with the appropriate approval procedures prior to initiation of the thesis related research, if approval is relevant to the research. The Institutional Review Board (IRB) at Meharry Medical College grants this approval, and therefore, can assist with detailed information, materials and guidance in the completion of the appropriate forms.

The goal of the Office of the SOGSR, as well as the student’s thesis committee, is to ensure that a document has been produced that will reflect, and properly represent, the student, the student’s committee, the graduate program, and the College.

TIMELINE

This is an outline of the timeline that should be adhered to as close as possible in the preparation of the MSPH thesis.

Semester	Activity
Fall Yr. 1	Step 1 (Planning) <ol style="list-style-type: none"> i. Brainstorm possible areas of interest (Aug-Oct) ii. Read standard text regarding each topic (Aug-Oct) iii. Read at least 10 articles in each area (Aug-Oct) iv. Select an area of interest (Nov) v. Identify mentor within your area of interest (Nov)
Spring Yr. 1	Step 2 (Thesis Committee) <ol style="list-style-type: none"> i. Work with mentor to write concept paper (March) ii. Identify Thesis Committee (April)
Fall Yr. 2	Step 3 (Preliminary Work) <ol style="list-style-type: none"> i. Work with committee to select topic/title (Sept) ii. Read the research done within your area (Sept) iii. Write a brief sketch for proposal (Sept) iv. Final proposal completed (Sept) v. Consent forms, HIPAA Forms, Flyers (Sept) vi. Complete and submit IRB application (Sept) vii. Ch 1: Introduction (Sept) viii. Determine appropriate sample size and statistical method (Oct) x. Identify secondary data set or develop data collection tool(Sept) xi. Ch 2: Literature Review (Oct)
Fall Yr. 2	Step 4 <ol style="list-style-type: none"> i. Pilot data collection tool (Oct) ii. Development of data collection spreadsheet (Oct) iii. Data Collection (Oct-Nov) iv. Ch 3: Methodology (Nov) v. Ch 4: Results/Descriptive and analytical data analysis (Dec) vi. Tables and graphs (Dec)
Spring Yr. 2	Step 5 <ol style="list-style-type: none"> i. Ch 5: Discussion of Results (Jan) ii. Submit degree application forms (Jan) iii. Second draft (Feb) iv. Third draft (Mar) v. Obtain approval to defend from Thesis Committee (Note: Thesis Committee must "read and approve" a document before a defense can be scheduled) vi. Obtain approval to defend from MSPH Director (minimum of two weeks before defense) vii. Defense (March-April) viii. Graduate (May)

Thesis Research Committee

Chairperson

The committee chairperson must have some experience in the area in which the student is interested in exploring. The chair may or may not be the mentor. The chair must be a full time faculty member from the DPHP graduate program.

Thesis Committee

In addition to the chairperson of the THESIS COMMITTEE, the student must select a minimum of two other persons to serve on the committee. At least one of these two additional faculty members must be a member of the DPHP faculty or a Meharry faculty with expertise in the area on which the thesis concentrates. If a non-Meharry person is selected for the committee, he/she must have expertise in the area on which the thesis concentrates and be approved by the Director of the MSPH program.

Mentor

Many students identify a mentor by becoming involved in graduate assistant work on an existing project with Meharry Medical College faculty, contacts at Vanderbilt University, or local agencies and organizations. To find a mentor it is advised for students to spend time attending lectures at the college and local conferences to determine what research is being done and to identify possible areas of interest. Students may also talk to faculty or administration to get information on organizations and individuals involved in projects, of interest. Second year students are a good source of information and may be able to point you in the right direction. Your mentor may serve on your thesis committee.

Individuals agree to be on the student's thesis committee by signing the THESIS COMMITTEE form (see appendix). By signing the form and taking on this responsibility, each individual on the Committee agrees to be knowledgeable about the standards set by the SOGSR and to abide by these standards. It is the responsibility of the student to make sure that each individual is aware of these standards. The Director of the MSPH Program and the Dean of SOGSR must approve all THESIS COMMITTEE members for a student. It is suggested to include both an epidemiologist and a statistician on the thesis committee.

CONCEPT PAPER

A student must prepare a concept paper to present to potential members of his/her thesis committee. This concept paper is no more than 2 double-spaced pages that must contain an introduction, objectives, review of literature, methodology and references. If necessary, references may be on one additional page. When possible, the concept paper should include the student's mentor and contact information. The purpose of the concept paper is to give the reader a short overview of what, why, and how the research is to be conducted and to encourage the reader to be a member of the student's thesis committee.

PROPOSAL

After the thesis committee has been formed, the student works with his/her committee to develop a 2-4 double spaced proposal (longer if thesis committee dictates) to be presented to the Institutional Review Board (IRB) for approval. This proposal topic may be slightly altered or different from the one presented in the concept paper. Once approved by the thesis committee, the proposal is submitted to the Meharry Medical College IRB in addition to the other IRB requirements. It is to contain an introduction, problem statement, aims (goals), objectives, hypothesis (if any), literature review, methodology, and references. If necessary, references may be on one additional page. This proposal should be clear and complete so that members of the IRB committee have a good understanding of the research project of the student.

IRB forms can be found on Meharry's website at www.mmc.edu. Click on Research and follow the link to Research Compliance.

Note: You may call Cynthia Weaver at 327-6735 for IRB information

INSTITUTIONAL REVIEW BOARD (IRB)

The IRB at Meharry Medical College is an administrative body established to protect the rights and welfare of human research subjects recruited to participate in research activities conducted at Meharry Medical College and to ensure institutional compliance with those ethical considerations contained in the Code of Federal Regulations. The IRB maintains guiding principles and operating policies demanding the highest professional standards in dealing with human subjects, and reviews all research projects involving human subjects to ensure that appropriate standards are met and research procedures do not infringe upon the safety, health, welfare or life of those subjects.

There are three levels of review:

- I. Exempt**
 - De-identified research participants
 - Secondary data set
- II. Expedited**
 - Primary data collection
 - Research participants are identifiable, but protected by unique ID number
- III. Full**
 - Same criteria as expedited
 - Collection of specimens or genetic materials
 - Invasive procedures
 - Deception
 - Vulnerable populations

All research proposals involving human subjects must be reviewed and approved by the Meharry Medical College IRB. The involvement of human subjects in research is not permitted until the IRB has reviewed and:

- Approved the research proposal
- Approved the informed consent form(s)
- Approved advertisements and survey instruments

Once approved, any changes to the protocol must be reviewed by the IRB prior to implementation, based upon the category of review.

ACADEMIC RESPONSIBILITY

Student's Responsibility

It is the student's responsibility to learn the policies, rules and regulations of both the DPHP and the SOGSR relative to the thesis writing. The student is also responsible for:

1. Choosing a thesis chairperson following the policies and guidelines of the Division.
2. Choosing the members of the thesis committee following the policies and guidelines of the Division.
3. Meeting with the chairperson and setting a schedule of appointments to discuss the student's progress and delineating a realistic time frame for completion of the thesis in a timely manner.

4. Meeting with his/her total thesis committee on a regular basis
5. Keeping the scheduled appointments.
6. Turning in all thesis materials to the total committee typed and in the proper formats.
7. Knowing and meeting all deadlines relative to the thesis process and graduation.
8. Filing all forms in a timely manner.

Note:

The faculty and staff of the SOGSR and the DPHP Training Program are available to assist students in their matriculation through the MSPH Program. They will let the students know how they are progressing and keep them abreast of important deadlines. They will also aid students in the preparation of the thesis. They should have a copy of this *Guide*, and discuss content and proper format of the thesis with the students for accuracy. The faculty will do their best to communicate with students in a timely manner. Please remember, however, that it is **ultimately the graduate student's responsibility** to know, understand, and meet the requirements established by the SOGSR and the DPHP Training Program.

THESIS ELEMENTS AND STYLE

FORMATTING AND TECHNICAL POINTERS

Type Face or Font

Typeface affects the physical appearance of the thesis more than any other single element. Word processing software packages provide the opportunity to use different typefaces (i.e. Arial, Times New Roman, New York, Geneva, etc.), type sizes, and font attributes, such as bold or italics. The size of type is determined by point size. Text is most readable in 10, 11 or 12 point, so these sizes are highly recommended in the thesis. The SOGSR prefers Times New Roman - 12 or Arial – 11.

The type face/font selected for text will be the base style or the "starting point" for all type/font selection and will establish the framework for the entire document. All of the following items must be in the same type/font selected as the "base" style:

- all preliminary pages, including approval sheet
- all text
- all tables -even those from other sources, provided they are called tables
- figure numbers and titles (the text within figures may be different typeface)
- all page numbers, including appendix page numbers

Type Quality

Acceptable type quality for the final master copy is determined by the following two factors: clean, crisp type with no distracting marks and dark copy indicating sufficient toner for readability.

Margin Settings and Justification

Thesis or dissertation margins must be strictly adhered to. The left margin must be no less than 1 1/2 inches; the right, top and bottom margins no less than 1 inch. All material included in the document, including text, tables, figures, page numbers, etc. must fit within these margins. All major headings in the preliminary pages and in the body must have a top margin of 2 inches. The approval sheet must have a top margin of 1 1/2 inches. These margins define the minimum white space to be maintained on all sides, because of the regulations set for binding. Although these margins are set to define white space, all space that is given should be used.

Note:

- 1) Typing may extend no more than one single space below the bottom marginal line, and only then to complete a footnote or the last line of a chapter, subdivision, or figure caption.
- 2) It is not permissible to leave a single line of a paragraph or other subdivision at either the bottom or the top of a page. The last word on a page cannot be hyphenated.

A type-written line, regardless of words in it that are exactly the same length as all other lines, is called "justified" (*Chicago Manual of Style*, p.61). Either "justified" or "ragged-right" margins are acceptable. The use of justified or ragged-right margins must be consistent throughout the document.

Spacing

Spacing has both aesthetic and utilitarian effects on the appearance of the document. Vertical spacing (or leading) determines the number of lines of text that will fit on a page and can make the thesis appear either cluttered or uncluttered, depending on the amount of space left between the lines. Horizontal spacing (or kerning) affects the spacing between letters of text, and, like leading, makes the spacing of proportional fonts appear disjointed or jointed. In each paragraph, there should be a double space between the end of the sentence and the beginning of the next sentence.

Most technical decisions about both vertical and horizontal spacing are determined by the word processing package. When a type face and size are selected, the default values for horizontal (kerning) are automatically set. Most word processing packages then allow the user to set the spacing for vertical measurement, using the predetermined line height as a basis. Single spacing leaves a small space between two lines of text, and doubling spacing leaves the equivalent of one line of text between two lines.

Standard double spacing is required for the document text. Most style manuals require single spacing to be used within long quotations, long tables, footnotes, multiple captions, and bibliographic entries. Double spacing should be used between footnotes and bibliographic entries.

In the event that extra space is needed (e.g., above headings, between numbering and title), an additional "enter" is added, doubling the white space. Paragraph indentions should be uniform throughout the thesis.

Pagination

Table 1 shows the sequencing and pagination of the various parts of the thesis. Small Roman numerals (i, ii, etc.), are used to number the preliminary pages. Although the preliminary paging begins with the title page, no number appears on this page. Therefore, the page following the title page should begin with the number ii. Beginning with the first page of the text, all pages should be numbered consecutively throughout the document, including the references, appendix, and vita, with arabic numerals (1, 2, etc.) beginning with the number 1. Pagination using letter suffixes (i.e., 10a and 10b) is not allowed. The numbers must be positioned 1 inch from the bottom of the page and centered within the margins.

Note:

- 1) For paper copies, the page number orientation must always be portrait orientation, even on pages that contain material that is landscape orientation.
- 2) The approval sheet is not numbered.

Consistency in Format

Consistency in formatting means that the student establishes a series of conventions or protocols regarding spacing, heading sequencing, and other aspects of appearance to visually guide the reader through the document, thus enabling the reader to concentrate on the content.

Arrangement of Thesis Parts

Table 1 shows the sequencing of the various parts of the thesis. There are parts in the sequencing that are denoted as being optional and these pages can be left blank.

Table 1. Arrangement of Thesis Parts

Thesis / Dissertation Parts	Page Assignment
Approval / Signature Sheet	No page number assigned

Preliminary Pages

Title page	Small Roman numeral "i" (assigned, not typed)
------------	--

*Copyright page/Blank page	Small Roman numeral Starting with number "ii" (Typed on page)
*Dedication page	
*Acknowledgments	
Abstract	
Table of Contents	
List of Tables (if 5 or more)	
List of Figures (if 5 or more)	
List of Abbreviations and/or Symbols (if needed; may be included as an appendix)	

Body of thesis (divided into chapters) <ul style="list-style-type: none">• Introductionf Literature Review• Methods• Results• Discussion	Arabic numerals, starting with 1
Separation Sheet	
Bibliography/ List of References	

*Separation sheet (if an appendix or appendices follow)	
*Appendix	
Vita	

*Note: Parts preceded by an asterisk are optional; all others are required.

Preliminary Pages:

The Preliminary Pages are sometimes called the “front matter.” These pages serve as a guide to the content and nature of the thesis. Samples of these pages are shown in the Appendix.

I. Approval Page (Required)

The approval acceptance sheet, is part of the preliminary pages, confirm acceptance by the committee members, the MSPH Director and the Dean of the SOGSR. Each copy of the thesis submitted to the SOGSR must have an approval page using the exact wording and format shown on the sample page. This sheet must be on the same brand and weight of cotton paper and be in the same base typeface as the remainder of the thesis. The name used on the approval page and title page must be that under which the student is registered at the institution. Each approval page must bear *(all) original signatures* of committee members. *Black ink is required for the original signatures*, preferably with the same pen. The number of signature lines for the committee members must equal the number of committee members. The major and degree to be awarded must be exactly those to which the SOGSR officially admitted the student.

II. Title Page (Required)

This page is assigned Roman number “i,” although the number does not appear on the page. The date used is the month and year of commencement. The student’s name must appear as he/she is registered at the institution. The wording and format must be exactly as shown on the sample page.

III. Copyright Page (Optional)

Students may wish to copyright their theses. If so, a copyright page can be used in the document. *Although this page is not mandatory, it is strongly recommended, because it informs the public that the work is protected by copyright.* The thesis can be formally copyrighted by downloading a form from the U.S. Government's Official copyright website: <http://lcweb.loc.gov/copyright/>. This constitutes publication and makes the thesis available to the public. *The Chicago Manual of Style* offers an excellent discussion of copyright law and its implications. "Copyright law exists to protect the exclusive right of the copyright holder to copy the work . . . [although] the law has long been interpreted as allowing others to copy brief portions of the work for certain purposes." If copyrighted material is used in a limited way, permission to quote usually need not be sought. If, however, extensive material from a copyrighted work is to be used such that the rights of the copyright owner might be violated, permission of the owner must be obtained. In determining the extent of a written work that may be quoted without permission, the student should consider the proportion of the material to be quoted in relation to the substance of the entire work. According to *The Chicago Manual of Style* "A few lines from a sonnet, for instance, form a greater proportion of the work than do a few lines from a novel. Use of anything in its entirety is hardly ever acceptable". In no case should a standardized test or similar material be copied and included in a thesis/dissertation without written permission. The publisher usually has the authority to grant permission to quote excerpts from the copyrighted work or can refer requests to the copyright owner or designated representative. The copyright owner may charge for permission to quote.

The following information must appear centered (*vertically and horizontally*) on the copyright page:

Copyright © _____(name), 20__(year)
All rights Reserved

IV. Dedication Page (Optional)

If the student wishes to dedicate the thesis, the statement is included on this page. The dedication statement should be *no more than five lines*.

V. Acknowledgements (Optional)

This page is to thank those who have helped in the process of obtaining the graduate degree. Permissions to quote copyrighted material are listed here, as well as acknowledgments for grants and special funding. The acknowledgement should be *no more than seven lines*. If a student can not restrict their acknowledgements to seven lines, the additional acknowledgements can be placed in the appendix.

VI. Abstract (Required)

The abstract of the masters' thesis should be a concise review of the work containing a brief summary of the problem and the results of the research. The following information is typically contained in the abstract:

- (1) A short statement concerning the area of investigation
- (2) A brief discussion of methods and procedures used in gathering the data
- (3) A condensed summary of the findings and conclusions reached in the study
- (4) Conclusions reached in the study

VII. Table of Contents (Required)

The Table of Contents may vary in style and amount of information included. Chapter or Section titles, the Bibliography or List of References, the Appendix, if any, and the Vita must be included. Page numbers given for the Bibliography and Appendix should be those assigned to the separation sheet preceding each of those items. Although it is not necessary to include all levels of headings, inclusion must be consistent. If a particular level is included at any point, all headings of that level must be included. *No preliminary pages with Roman numerals are included in the Table of Contents; the Table of Contents entries start with page 1.*

VIII. List of Tables (If necessary)

If there are five or more tables, a List of Tables must be included. Any tables appearing in the appendix are also included in the appropriate list. The title of each table must be different, and all titles must be entered in the list worded exactly as they appear in the tables. This includes information up to the first terminal punctuation.

A table consists of numbers, word, or both and presents information that is separated into columns. Tabular information allows the author to convey precise information to a reader in structured format.

IX. List of Figures (If necessary)

If there are five or more figures, a List of Figures must be included. Any figures appearing in the appendix are also included in the appropriate list. The title of each figure must be different, and all figures must be entered in the list worded exactly as they appear in the figures. This includes information up to the first terminal punctuation.

Any diagram, drawing, graph, chart, map photograph, or material that does not fit into the restricted format for table is a figure or plate. Figures generally show relationships or illustrate

information rather than present precise data. Plates are a subgroup of figures and usually consist of groups of separate photographs or drawings presented together.

X. List of Abbreviations (If necessary)

The title of this material should reflect its content and may be included to define specialized terms or symbols. This information may also be placed in an appendix.

Text:

Text is used as a generic term to designate the main body of the thesis and to distinguish this element from the preliminary pages, references, tables, figures, and appendices.

The following is a checklist of items which are typically included in a research thesis, dissertation or report. Not all of the suggested categories are necessary or appropriate for all studies, and the order of items within chapters may vary somewhat. Those items with an X next to them are strongly suggested to be included in the thesis of a MSPH student. These items are intended to serve as a guide:

CHAPTER I: THE INTRODUCTION (THE PROBLEM)

- _____ Introduction
- X Background of the problem (e.g., educational trends related to the problem, unresolved issues, social concerns)
- X Statement of the problem situation (basic difficulty-area of concern, felt need)
- X Purpose of the study (goal oriented) – emphasizing practical outcomes or products
- X Questions to be answered or objectives to be investigated
- _____ Conceptual or substantive assumptions (postulates)
- X Rationale and theoretical framework (when appropriate)
- X Delineation of the research problem (explication of relationships among variables or comparisons to be considered)
- X Statement of hypotheses (conceptual rendition subsequently followed by operational statements in Chapter I or in Methodology Chapter) Importance of the study-may overlap with statement of problem situation
- X Definition of terms (largely conceptual here; operational definitions may follow in Methodology Chapter)
- X Scope and delimitations of the study (narrowing of focus)
- _____ Outline of the remainder of the thesis or proposal

CHAPTER II: LITERATURE REVIEW

- _____ Organization of the present chapter – overview
- _____ Historical background (if necessary)
- Purpose to be served by Review of Research Literature
- X Acquaint reader with existing studies relative to what has been found, who has done work, when and where latest research studies were completed, and what approaches involving research methodology, instrumentation, and statistical analyses were followed (literature review of methodology sometimes saved for chapter on methodology)
- _____ Establish possible need for study and likelihood for obtaining meaningful, relevant, and significant results

- X Furnish from delineation of various theoretical positions a conceptual framework affording bases for generation of hypotheses and statement of their rationale (when appropriate)
- Note: In some highly theoretical studies the chapter "Review of Literature" may need to precede "The Problem" chapter so that the theoretical framework is established for a succinct statement of the research problem and hypotheses. In such a case, an advance organizer in the form of a brief general statement of the purpose of the entire investigation should come right at the beginning of the "Review of Literature" chapter.

Sources for Literature Review

- General integrative reviews cited that relate to the problem situation or research problem such as those found in *Review of Educational Research, Encyclopedia of Educational Research, or Psychological Bulletin.*
- X Specific books, monographs, bulletins, reports, and research articles-preference shown in most instances for literature of the last ten years
- X Unpublished materials (e.g., dissertations, theses, papers presented at recent professional meetings not yet in published form, but possibly available through ERIC)
- Selection and arrangement of literature review often in terms of questions to be considered, hypotheses set forth, or objectives or specific purposes delineated in problem chapter
- Summary of literature reviewed (very brief)

CHAPTER III: METHODS (METHODOLOGY OR PROCEDURES)

- Overview (optional)
- X Description of research methodology or approach (e.g., experimental, quasi-experimental, correlational, causal-comparative, or survey)
- X Research design (Spell out independent, dependent and classificatory variables and sometimes formulate an operational statement of the research hypotheses in null form so as to set the stage for an appropriate research design permitting statistical inferences.)
- X Pilot studies (as they apply to the research design, development of instruments, data collection techniques, and characteristics of the sample)
- X Selection of subjects (This is concerned with sample and population.)
- X Instrumentation (tests, measures, observations, scales, and questionnaires)
- Field, classroom or laboratory procedures (e.g., instructions to subjects or distribution of materials)
- X Data collection and recording
- X Data processing and analysis (statistical analysis)
- X Methodological assumptions
- Limitations (weaknesses)
- X Possible restatement of conceptual hypotheses from problem chapter in operational form relative to instrumentation and experimental procedure or design followed (operationally stated hypotheses can also be put in null form to furnish an optional third set of hypotheses amenable to statistical testing) – if not done elsewhere.
- Summary (optional)

CHAPTER IV: RESULTS (FINDINGS, ANALYSIS AND EVALUATION)

- X Findings are presented in tables or charts when appropriate

<u> X </u> <hr/>	Findings reported with respect to furnishing evidence for each question asked or each hypothesis posed in problem statement Appropriate headings are established to correspond to each main question or hypothesis considered
<u> X </u> <i>Note:</i> <hr/>	Factual information kept separate from interpretation, inference, and evaluation (one section for findings and one section for interpretation or discussion) In certain historical, case-study and anthropological investigations, factual and interpretive material may need to be interwoven to sustain interest level, although the text should clearly reveal what is fact and what is interpretation. Separate section often entitled "Discussion," "Interpretation," or "Evaluation" ties together findings in relation to theory, review of literature, or rationale Summary of chapter

CHAPTER V: DISCUSSION (SUMMARY, CONCLUSIONS, RECOMMENDATIONS)

<u> X </u>	Brief summary of everything covered in first three chapters and in findings portion of Chapter IV
<u> X </u>	Conclusions ("so what" of findings; often the hypotheses restated as inferences with some degree of definitive commitment and generalizability)
<u> X </u>	Recommendations (practical suggestions for implementation of findings or for additional research)

Bibliography/List of References:

A thesis must include a list of citations used in the preparation of the thesis. This may consist only of references cited in the text (List of References) or it may include works consulted as well (Bibliography). A numbered page with the title -- Bibliography or List of References -- centered vertically and horizontally, precedes the list. The purpose of listing the citations is threefold:

- (1) To serve as an acknowledgment of sources
- (2) To give readers sufficient information to locate the volume
- (3) In the case of personal interviews or correspondence, to save readers the trouble of attempting to locate material that is not available.

Reference software such as *Endnotes* or *Reference Manager* is available to make managing your references easier. The disk with *Endnotes* is available to students in the SOGSR.

Appendix:

An appendix (appendixes or appendices) is generally a "catch all" for supplementary material to the thesis. In some cases, tables and or figures are placed in the appendix to avoid interrupting the text. If included, is preceded by a numbered page with the designation centered vertically and horizontally between the margins. Original data and supplementary materials are usually placed in the appendix.

Vita:

The vita is written in narrative or outline form and contains appropriate personal, academic and professional information about the author. Since copies of the manuscript will be available to the public, private information should not be included. It is the last item in the manuscript and appears with no preceding separation page and no page number.

As the final section of the thesis, the writer must prepare a biographical sketch of himself or herself in paragraph form, or in outline form. The vita should contain, but is not limited to, the following items:

- (1) Full name, date of birth, and parents of the candidate, if desired
- (2) High school and colleges attended with dates and dates of degrees
- (3) Honors and major interests
- (4) Military and work experience
- (5) Career and objectives
- (6) Teaching experience
- (7) Publications
- (8) Presentations
- (9) Community Service

Process for Thesis Public Defense

Process for the MSPH Student Thesis Defense

The student must successfully defend the thesis research in a public seminar presented on a weekday between 8:00 a.m. and 5:00 p.m. and it must be widely publicized. Thus, the student must work with the Thesis Committee Chair and submit the title, date, plus abstract and chapters 1-5 of the thesis to the MSPH Director two weeks before the defense. All members of the Thesis Committee must agree that the student is ready to publicly defend. The process for this defense is as follows:

1. Thesis Committee members agree, after they have read and approved the thesis that the student is ready to defend.
2. Thesis Committee with information from the student determines the tentative defense date.
3. Thesis Committee Chair contacts MSPH Director a minimum of two weeks in advance of the proposed student's defense date to:
 - a. Inform the Director that the student is ready to defend thesis by completing and submitting the *MSPH Thesis Defense Application Form* with signatures of all committee members,
 - i. Provide the Director with the requested date, time, room (Utmost Bound) and,
 - ii. Provide the Director with the title, abstract of the thesis, and Chapters 1-5.
4. MSPH Director confirms the availability of the date, time and room for the requested defense with the SOGSR.
5. The Director will inform the Thesis Committee Chair about the availability of the date, time, and room for the defense.
6. If the date, time, and room are available for the defense as requested, the MSPH Director will provide the following information to the Dean's Office:
 - a. The date, time and room for the defense,
 - b. The title of the thesis,
 - c. Copy of the thesis abstract,
 - d. Chapters 1-5
7. The Dean's Office will prepare the flyers for advertisement of the defense and coordinate the distribution of the flyers on campus,
8. Prior to the defense, the student will obtain from the SOGSR the thesis defense evaluation form to give to the Thesis Committee chair for the defense.

9. Student defends the thesis.
10. Thesis Committee evaluates student's defense.
11. The Committee Chair provides the Director with the score of the defense on the *Quality of the Thesis Defense* form signed by all members of the Thesis Committee.
12. After the student has completed writing the thesis, the Committee uses the *Quality of Written Thesis* form to evaluate the written thesis.
13. The Chair of the Thesis Committee provide the Director with the score of the written thesis on the *Quality of Written Thesis* form signed by all members of the Thesis Committee

The decision of the Thesis Committee is considered by the SOGSR to be final with approval of the MSPH Director and Dean. The deadlines for public defenses and their respective graduation dates are listed in the table below.

Public Defense Deadline	Graduation (Degree) Date
April 15	May
May 15	June
July 15	October
October 15	December

Basic Process for the Oral Defense

The basic process for an oral defense of a thesis is summarized below.

- (1) The candidate presents his or her argument, summarizing the main points of the study.
- (2) The chairperson then allows other members of the committee and the audience to direct questions to the candidate concerning the research.
- (3) Following the candidate's presentation and the fielding of questions, the candidate is excused from the room so that the Chairperson and members of the committee may discuss and subsequently vote on the candidate's success or failure.
- (4) The candidate is escorted into the room to receive the results of the committee's vote.
- (5) The evaluation score of the defense is indicated on the Thesis Defense evaluation form completed and signed by all members of the THESIS COMMITTEE Committee (Thesis Committee).
- (6) The signed Thesis Defense evaluation form is forwarded on to the Director of the MSPH Program

Evaluation of Written Thesis

Throughout the writing of the thesis the student takes the lead in providing the content and making sure the thesis is correct in terms of grammar, punctuation, format, and other requirements of the thesis. The THESIS COMMITTEE provides guidance in assuring that these obligations for the thesis are correct. Before final submission of the thesis to the SOGSR, the THESIS COMMITTEE evaluates the quality of the written thesis, inform the student of the evaluation score. Afterward, the Written Thesis Evaluation form is forwarded to the Director of the MSPH Program.

THESIS SUBMISSION

Submission

An approved unbound draft copy of the thesis must be submitted to the School of Graduate Studies and Research no later than when the student submit his/her MSPH Thesis Defense Application Form. However, it is suggested that the student submit drafts of the thesis as early as possible after receiving approval for the respective chapter(s) from his/her thesis committee. Each student is responsible to be knowledgeable of thesis deadlines established by the MSPH program. When this document is submitted prior to the submission of the MSPH Thesis Defense Application Form, it should be placed in a manila envelope with the following information in the upper left corner:

- Student's name
- Thesis title in full
- Distinction of which draft (first or second draft)
- Chairperson
- Graduation date
- Phone number

The thesis will be reviewed to determine format and compliance with this *Guide to Thesis Preparation*, quality of reproduction, and other matters of format and style. If revisions of the thesis are necessary, the student must incorporate the changes and resubmit the document. The last revised version of the thesis that is error free must be submitted to the SOGSR by the last Friday in April for May graduation, May for June graduation, August for October graduation, or October for December graduation.

Submission of a thesis to the SOGSR should not be interpreted as approval from the MSPH Director or Graduate Dean. Approval comes only after the document is read and the format reviewed for consistency with the thesis guidelines. The final copy of the thesis must be acceptable to all members of the committee, the MSPH Director and the Graduate Dean as witnessed by the signatures on the approval page.

The SOGSR will bind the copies and will distribute one to the MSPH Program, Meharry Medical College library, and Graduate Dean's Office. Other copies may include one for the Chair of the Committee, one for the student, and other copies requested by the student. These other copies of the thesis, including any required by the department, are bound through arrangements made by the SOGSR, and will cost \$30.00 each.

Paper and Duplication

A minimum of five (5) unbound copies of the thesis must be produced using a laser printer or photocopier. Inkjet, dot matrix or bubble-jet printers cannot be used to produce the final copies of the document. The final paper copies are one-sided copies printed on 100% cotton, at least 20-pound weight, white paper. Any brand of paper can be used, but the same brand must be used throughout all copies, including the approval sheets. Acceptability of these copies and the quality of reproduction is determined solely by the SOGSR. The reproduction of each page must be sharp and clear; each page must also be free from smudges and extraneous marks. Be sure to inspect each page of the five copies very carefully before accepting the five copies from a photocopying or reproduction company.

TIPS FOR WRITING

When you are about to begin, writing a thesis seems a long, difficult task. One key to success is to adopt a systematic approach to achieve your goal.

I. PREPARE AN OUTLINE

- A. Create an outline
 - 1. Chapter headings
 - 2. Sub-headings
 - 3. Figure titles
 - 4. Notes and comments
- B. Discuss your outline with the chairperson of your committee.
- C. Give the chairperson of your committee a copy of your outline for reference.

II. BE ORGANIZED

- A. Have a computer filing system.
 - 1. Open a computer document for each chapter and one for the references.
 - 2. Make a back up of these files and do so daily
 - 3. Never underestimate the potential for fire or water damage.
 - 4. You should also have a rotating master back up.
 - a. Use two disks; back-up one of them every week.
 - b. Email each updated version to yourself as an attachment.
- B. Have a physical filing system.
 - 1. A collection of folders with chapter numbers on them.
 - a. This will make you feel good about getting started.
 - b. It also helps keep you desk clean.
 - 2. Have a file for the plots of results and pages of calculations.
 - 3. Have a file for old notes, references, speculations, etc.
 - 4. Put all of your folders in a box or a filing cabinet.
- C. Making Copies.

If any of your data exist only on paper, copy them and keep the copy in a different location. Consider making a copy of your data book. Ethics may require you to keep original data for at least ten years, and a copy is more likely to be found if two copies exist.

III. CREATE A TIMETABLE

- A. Agree with the chairperson on a timetable for writing the manuscript.
 - 1. A list of dates for completing drafts of each chapter may be helpful.
 - 2. A list of dates for your chairperson to return with comments and corrections may be helpful.
 - 3. A date for completion is essential.
- B. Meet your deadline!

Whenever you sit down to write, it is very important to write something. So write something, no matter how rough. It is often easier to improve something that is already written than to produce text from nothing. So develop a draft then clean it up for your chairperson to read.

Your chairperson will expect to read each chapter in draft form. It will be returned to you with suggestions and comments. Do not be upset if a chapter --- especially the first one you write --- is returned covered in red ink. Your chairperson will want your work to be as good as possible, because their reputation as well as yours is affected.

So take a positive attitude to all the scribbles with which your advisor decorates your text.

As you write your thesis, you will notice an enormous improvement in the initial drafts from the first to the last chapter written. Remember, only the final draft is assessed: the more comments your chairperson adds to first or second draft, the better.

Before you submit a draft to your chairperson, run a grammar and a spell check. If you use a result, observation or generalization that is not your own, you must usually state where in the scientific literature that result is reported. The only exceptions are cases where everyone knows it: dynamics equations need not precede a citation of Newton. The importance of this practice in science is that it allows the reader to verify your starting position. Good referencing also tells the reader which parts of the thesis are descriptions of previous knowledge and which parts are your additions to that knowledge. In a thesis written for the general reader who has little familiarity with the literature of the field, this should be especially clear.

APPENDICIES

. Sample Concept Paper

Lauren McCullough, BA
Meharry Medical College – MSPH Candidate
lmccullough@mmc.edu

Introduction

During the course of my studies I have become involved in research taking place at Vanderbilt Medical Center's – Center for Health Services Research. Under the direction of Dr. Charles Matthews I am currently assisting with two small studies involving both physical activity and cancer. Being involved in this work has allowed me to gain experience in the full spectrum of the research enterprise, from participant recruitment, eligibility determination, and baseline data collection, through follow-up and data analysis. Moreover, I have been exposed to a wealth of knowledge concerning breast cancer patients and the effects of adjuvant chemotherapy on these individuals.

Thesis Topic

Factors that facilitate in adherence to a 12 wk walking intervention among breast cancer patients: A time to event analysis.

Aims and Objectives

The objectives this study are to; 1) Determine what factors most greatly influence adherence to an exercise intervention in breast cancer survivors. 2) Estimate the probability of achieving the desired outcome, increased physical activity level, of breast cancer survivors within a 3-month period. 3) Allow researchers and clinicians alike the ability to detect those individuals whom are at greatest risk for a low physical activity following adjuvant chemotherapy. Detection of at-risk individuals or groups will facilitate the ability of caregivers to provide remedial work based on prediction results.

Hypothesis

I hypothesize that those factors that most significantly contribute to adherence are low perceived barriers, high self-efficacy, high social support, and increased time. I expect that these women will not experience the critical event (no adherence) during the 3-month period and anticipate these individuals to have higher quality of life indicators for physical status and maintain healthier body weight.

Literature Review

Over the years there has been an increase in the incidence of breast cancer. Through the development of innovative and improved screening and treatment options the survival of the disease has also increased. Those factors contributing to survival are important in developing new treatments and means of prevention ultimately helping to reduce incidence and enhance survival and quality of life following remission. Diagnosis and treatment of breast cancer are associated with several adverse physical outcomes e.g., weight gain, reduced physical activity levels, and loss of lean body mass (Lindsey 2004). It has been suggested that regular physical activity participation may attenuate the adverse effects thus improve health, breast cancer risk, and overall quality of life (King 2006).

Aims and Objectives

The objectives this study are to; 1) Determine what factors most greatly influence adherence to an exercise intervention in breast cancer survivors. 2) Estimate the probability of achieving the desired outcome, increased physical activity level, of breast cancer survivors within a 3-month period. 3) Allow researchers and clinicians alike the ability to detect those individuals whom are at greatest risk for a low physical activity following adjuvant chemotherapy. Detection of at-risk individuals or groups will facilitate the ability of caregivers to provide remedial work based on prediction results.

Data Collection and Statistical Analysis

The study will use a secondary data set provided by the Vanderbilt-Ingram Cancer Center. SPSS and SAS statistical programs will be used in performing both multiple linear and logistic regression analyses.

Methodology (add paragraph on Methodology)

I am seeking your expertise in helping me to successfully complete and defend my thesis in the spring of 2007. Please let me know at your earliest convenience if you are able to assist me in my research.

(Date) *II. Informed Consent Form*
Meharry Medical College

Informed Consent to Participate in Research

Title: Title of protocol.

Principal Investigator: Include name of P.I. and other investigators as appropriate.

Introduction/Background/Purpose: (Required in all consent forms) May be one or more sections; modify heading(s) as appropriate.

Federal Regulation: "...The following information shall be provided to each subject: (1) a statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation...." [45 CFR 46.116(a)(1) and for research subject to FDA regulation 21 CFR 50.25(a)(1)] When appropriate, the consent form should also state "the approximate number of subjects involved in the study. [45 CFR 46.116(b)(5) and 21 CFR 50.24(b)(5)]

This part of the consent form must include:

- A statement that potential subjects are being asked to volunteer for a research study
- An explanation of why the subject is being asked to volunteer.
- A clear explanation of the purpose of the research.
- The expected duration of the subject's total participation, and
- The approximate number of patients to be enrolled in the study and elsewhere. (Not required unless the number of subjects is material to the subject's decision to participate; e.g., small sample size might compromise confidentiality.)

Procedures: (Required in all consent forms)

Federal Regulation: "...The following information shall be provided to each subject: (1) "...a description of the procedures to be followed, and identification of any procedures which are experimental." [45CFR 46.116(a)(1) and 21 CFR 50.24(a)(1)]

This section must include:

- A detailed description and explanation of the procedures that will be performed on the subject, e.g. filling out questionnaires, being interviewed, being audio or videotaped, engaging in role playing, performing computerized experiments, etc.
- A full explanation of all responsibilities and expectations of the subject. Be sure to communicate the following:
 - All of the different people with whom the subject will interact with, if applicable.
 - Where the research will be done.
 - When the research will be done.
 - How often the procedures will be performed.
 - How much of the subject's time will be involved in each session, and in total
- A statement of how the subject will be compensated for their time and expenses (i.e., cash, coupons, t-shirt, etc.). If none, explain there is no compensation.

Benefits: (Required in all consent forms)

Federal Regulation: "...The following information shall be provided to each subject: (3) a description of any benefits to the subject or to others which may reasonably be expected from the research." [45 CFR 46.116(a)(3) and 21 CFR 50.25(a)(3)]

This section should include a statement that there may be no benefit to the subject. Any benefits to the subject or others that can be expected should be described, but in a way that is not coercive, enticing, or self-serving. Benefit to society is appropriate. Do not refer to financial compensation in this section.

Costs of Treatment: (Required in all consent forms)

A description of costs (research and standard care) and who is responsible for payment.

Risks: (Required in all consent forms)

Federal Regulation: "...The following information shall be provided to each subject: (2) a description of any reasonably foreseeable risks or discomforts to the subject." [45 CFR 46.116(a)(2) and, 21 CFR 50.25(a)(2)].

Alternative Procedures: (Required in all consent forms).

A disclosure of any alternative procedures which might be advantageous to the subject.

Compensation: (Required in all consent forms)

(This section is required for projects that involve greater than minimal risk).

Federal Regulation: "...The following information shall be provided to each subject: (8) an explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research related injury to the subject." [45 CFR 46.116(a)(7) and 50CFR 21.25(a)(7)]

Confidentiality: (Required in all consent forms)

Federal Regulation: "...The following information shall be provided to each subject: (5) a statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained." [(45 CFR 46.116(a)(5)]

The following is acceptable wording for this statement; it should be modified as appropriate:
We will keep your records private to the extent allowed by law. We will use [a study number, your initials*] rather than your name on study records where we can. Your name and other facts that might point to you will not appear when we present this study or publish its results.

*Include or omit as appropriate.

Subject Rights: (Required in all consent forms)

Federal Regulation: "A copy [of the consent form] shall be given to the person signing the form." [45 CFR 46.117(a) and 21 CFR 50.27(a)]

Voluntary Participation and withdrawal is incorporated into the "Subject Rights" section. Federal Regulation: "...The following information shall be provided to each subject: (8) a statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled. [45 CFR 46.116(a)(8) and 21 CFR 50.25(a)(8)]

PLEASE PROOF READ!

Look for the following:

- Spelling, typographical and grammatical errors
- Consent forms should never be written in first person. ("I am being asked to be in a research study...."). The committee prefers 2nd grammatical person when the person signing the consent form is always the study subject. Be sure the document consistently refers to the potential study subject as "you." If the study is such that consent will be obtained from someone other than the actual subject (e.g., a parent, next of kin, or legal guardian) the consent form should be written in the 3rd person (e.g., "Participants in this study will undergo the following tests and procedures.") This is especially true if the consent form sometimes will be given to the subject, and sometimes to a parent or guardian. Avoid the following style: "If you (your child) agree/agrees to participate in this study you/he/she will have the following tests and procedures performed."
- Technical/advanced language – When writing the consent form, aim for an 8th grade level. Most word processors include utilities in the "Tools" menu to analyze the reading level of text. Use these tools!
- Write in short declarative sentences. Use simple words of fewer than three syllables whenever possible.
- Avoid long complex sentences.
- Avoid using technical terms as much as possible. If you must use technical terms, explain what they mean in lay language.
- Include a version date and page numbers.
- Avoid using "You understand..." It implies the subject understands more than he/she may comprehend. It can be interpreted as suggestive and can constitute coercive influence over a subject.

III. Sample Informed Consent Form
INFORMED CONSENT TO PARTICIPATE IN RESEARCH

Principal Investigator:

Telephone No.:

Meharry Medical College

Dept.:

Title of Project:

You are being asked to volunteer as a participant in a research study. This form is designed to provide you with information about this study. (THIS STATEMENT IS REQUIRED)

PURPOSE: Explain the purposes of the research and the expected duration of the subject's participation.

PROCEDURES: Describe the procedures to be followed, expected duration, and identify any procedures which are investigational.

BENEFITS: Describe any benefits to the subject or to others.

COSTS OF TREATMENT: Describe any costs incurred by the study and who is responsible for payment.

RISKS: Describe any foreseeable risks or discomforts, including psychological, legal, or social risks.

ALTERNATIVE PROCEDURES: Describe alternative procedures which might be advantageous to the subject (if applicable).

COMPENSATION: (This section is required for projects that involve greater than minimal risk).

You should report any injury or illness, which you believe to be related to this research project to Jane Doe, M.D., Principal Investigator at 327-1234, or James L. Potts, M.D., Chair of the Meharry Institutional Review Board, at 327-6735. Medical treatment for injury of illness resulting from the research procedures is available at Metropolitan Nashville General Hospital. Payment for this medical treatment is your responsibility. Meharry Medical College, the research sponsor, and their agents and employees are not responsible for the payment of medical care or for compensation of any expenses associated with research-related illness or injury.

The above "Compensation" statement does not limit your legal rights. You do not waive any legal rights by signing this form.

CONFIDENTIALITY: Describe how data will be kept confidential, who will have access to data (include organizations that will have access, i.e. FDA), where data will be stored, and how long data will be stored.

SUBJECT RIGHTS: Any questions you have involving the research and your rights may be addressed to [insert Principal Investigator's name] at _____ or James L. Potts, M.D., chair of the Meharry Institutional Review Board, at 327-6735. Your participation in this study is

Voluntary and you are free to withdraw at anytime without penalty or loss of benefits that you are otherwise entitled to. You will be given a copy of this form to keep.

Signature of Participant

Date

Signature of Witness

Date

Signature of person who obtains consent

Date

Insert a space at the bottom of each page of the consent form for the subjects initials (Subject Initials _____), if the consent form is longer than one page. Number all pages; the total number of pages must be on each page (e.g. Page 1 of 4)

*IV. Sample IRB Approval Letter
Full Board Review*

Date

«PIFirstName» «PIMiddleName» «PILastName», «Degree»
Division of Public Health Practice
Meharry Medical College
Nashville, TN 37208

RE: FINAL IRB APPROVAL of «Title» («Sponsor» «SponsorNumber»)

Dear «Salutation» «PILastName»:

The Institutional Review Board approved the corrections and clarifications to the protocol and the consent form dated «CnsntFrmDate» for the project above. **Please use the enclosed consent form with the IRB stamp as the original for all copies of the consent form.**

The project and consent form were approved at the IRB's meeting on «MeetingDate»; this approval period ends on «Next_ExpDate» with the understanding that any changes in the protocol or consent form which affect human subjects (number of subjects, dosages, frequency of visits, etc) must be approved by the IRB before being implemented. During the course of the study, any local serious events, whether anticipated or unanticipated, must be reported to the IRB within 48 hours. Any serious adverse events that occur at other sites must be reported to the IRB within five working days. In the event that you or the sponsor closes or suspends the study, the IRB must be notified within five working days.

In «SndMatMY» you will be sent the material required for this project's periodic review, and the IRB will require a progress report at that time.

If you have any questions, please call me or Cynthia Weaver in the Office of Grants Management at 6735.

Sincerely yours,

Name of Chair
Chair

«ControlNumber»

V. Sample IRB Approval Letter
Expedited Review

Date

«PIFirstName» «PIMiddleName» «PILastName», «Degree»
Division of Public Health Practice
Meharry Medical College
Nashville, TN 37208

RE: «Title» («Sponsor» «SponsorNumber»)

Dear «Salutation» «PILastName»:

The Institutional Review Board (IRB) approved your proposal and consent form dated «CnsntFrmDate» for the project above by expedited review based on 45 CFR 46.110 category based on category. **Please use the enclosed consent form with the IRB stamp as the original for all copies of the consent form.**

The approval period ends on «Next_ExpDate» with the understanding that any changes in the protocol or consent form which affect human subjects must be approved by the IRB before being implemented. During the course of the study, any local serious adverse events, whether anticipated or unanticipated, must be reported to the IRB within 48 hours. Any serious adverse events that occur at other sites must be reported within five working days. In the event that you or the sponsor closes or suspends the study, the IRB must be notified within five working days.

In «SndMatMY» you will receive the material required for the project's continuing review and approval.

The IRB will need information regarding the implementation of the project and the results to date.

If you have any questions regarding this please feel free to contact me or the IRB office at 6735.

Sincerely,

«PrimaryReviewer»
IRB Member

«ControlNumber»

VI. Sample IRB Approval Letter
Exempt Review

Date

«PIFirstName» «PIMiddleName» «PILastName», «Degree»
Division of Public Health Practice
Meharry Medical College
Nashville, TN 37208

RE: «Title» («Sponsor» «SponsorNumber»)

Dear «Salutation» «PILastName»:

The Institutional Review Board has determined that the project above is exempt based on [i.e., category 45 CFR 46.101(b) (4) of the federal regulations concerning the use of existing records, data, pathological specimens or diagnostic specimens when the information is recorded by the investigator in such a manner that subjects cannot be identified.] No consent form is needed.

If you have any questions regarding this please feel free to contact me or Cynthia Weaver at 6735.

Sincerely,

«PrimaryReviewer»
IRB Member

«ControlNumber»

VII. Sample IRB Approval Letter
Exempt Review

Date

«PI FirstName» «PI MiddleName» «PI LastName», «Degree»
Division of Public Health Practice
Meharry Medical College
Nashville, TN 37208

RE: «Title» («Sponsor» «SponsorNumber»)

Dear «Salutation» «PI LastName»:

The Institutional Review Board has determined that the project above is exempt based on [i.e., category 45 CFR 46.101(b) (4) of the federal regulations concerning the use of existing records, data, pathological specimens or diagnostic specimens when the information is recorded by the investigator in such a manner that subjects cannot be identified.] No consent form is needed.

If you have any questions regarding this please feel free to contact me or Cynthia Weaver at 6735.

Sincerely,

«PrimaryReviewer»
IRB Member

«ControlNumber»

*VIII. INSERTION OF HUMAN SUBJECT REVIEW FORM (HSRF)
FOR FULL BOARD AND EXPEDITED REVIEW (DOC)*

INSERTION OF EXEMPT FORM (DOC)

Meharry Medical College

AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION FOR RESEARCH PURPOSES

{Project Title}

{Principal Investigator} – Principal Investigator

The privacy law, Health Insurance Portability & Accountability Act (HIPAA), protects your individually identifiable health information (protected health information). The privacy law requires you to sign an authorization (or agreement) in order for researchers to be able to use or disclose your protected health information for research purposes in the study entitled [*Insert title of study*].

By signing this, you authorize [*name of researcher*] and his/her research staff to use and disclose your protected health information for the purposes described below. You also permit your doctors and other health care providers to disclose your protected health information for the purposes described below.

Your protected health information that may be used and disclosed includes:

- [*List all of the protected health information* to be collected for this protocol/study such as demographic information, results of physical exams, blood tests, X-rays, and other diagnostic and medical procedures as well as medical history*]

Your protected health information will be used for:

- [*Provide a brief description of each research purpose or paste information from purpose section in the consent form; indicate that one reason to share the information is to be able to conduct the research, another reason is to ensure that the research meets legal, institutional or accreditation requirements*]

The Researchers may use and share your health information with:

- The Meharry Medical College's Institutional Review Board/Office of Research Support Services
- Government representatives, when required by law
- [*List any collaborators, outside laboratories, etc.*]
- [*If applicable – list the sponsor's name*]
- [*List any other groups with whom the information may be shared*]

* Name, Address, Dates Directly Related to an Individual, Telephone/Fax Number, E-mail/Internet Protocol or Web URL Address, Social Security Number, Medical Record or Health Plan Number, Account Number, Certificate of License Number, Photographic Images, Vehicle Identifiers, Device Identifiers, Biometric Identifiers, Any Other Unique Code

Once your health information has been disclosed to anyone outside of this study, the information may no longer be protected under this authorization.

The researchers [*and list sponsor's name if applicable*] agree to protect your health information by using and disclosing it only as permitted by you in this Authorization and as directed by state and federal law

You do not have to sign this Authorization. If you decide not to sign the Authorization:

- It will not affect your treatment, payment or enrollment in any health plans or affect your eligibility for benefits.
- You may not be allowed to participate in the research study.

After signing the Authorization, you can change your mind and:

- Not let the researcher disclose or use your protected health information (revoke the Authorization).
- **If you revoke the Authorization, you must send a written letter to: [*name and contact information*]** to inform him/her of your decision.
- If you revoke this Authorization your protected health information may still be used and disclosed should you have an adverse event (a bad effect).
- If you change your mind and withdraw the authorization, you may not be allowed to continue to participate in the study.

Note: You may not revoke authorization of the use and disclosure of the protected health information that had already been collected prior to revoking the authorization.

You will not be allowed to review the information collected for the research until after the study is completed. When the study is over, you will have the right to access the information again.

This Authorization does not have an expiration date.

If you would like a copy of the Privacy Notice, you may request one. If you have any questions or concerns about your privacy rights, you should contact the Meharry Medical College Privacy Officer at Ph: (615) 327-6102.

You are the subject or you are authorized to act on behalf of the subject. You have read this information, and you will receive a copy of this form after it is signed.

Signature of research subject or *research
subject's legal representative

Date

Printed name of research subject or
*research subject's legal representative

Representative's relationship to
research subject

*Please explain Representative's Relationship to Subject and include a
description of Representative's Authority to act on behalf of Subject:

X. Sample HIPPA APPROVAL LETTER
(Full Board)

DATE

«PIFirstName» «PIMiddleName» «PILastName», «Degree»
«Department»
Meharry Medical College
Nashville, TN 37208

RE: «Title» («Sponsor» «SponsorNumber»)

Dear «Salutation» «PILastName»:

The Institutional Review Board (IRB) approved the HIPAA authorization for the project above at its meeting on «MeetingDate». **Please use the enclosed HIPAA authorization with the IRB stamp as the original for all copies of the authorization.**

This approval is with the understanding that the use and disclosure of protected health information is consistent with the protocol and consent form. This approval is also with the understanding that the description of individuals, position of individuals, and institutions with whom protected health information will be shared is accurate. No additional use or disclosure of protected health information will be permitted without prior IRB approval. **The authorization does not have an expiration date and only needs to be re-submitted if there are changes in: 1) the type of protected health information collected; 2) the use of the protected health information or; 3) the disclosure of protected health information.**

If you have any questions regarding this please feel free to contact the IRB Office at 6735.

Sincerely,

Primary Reviewer
IRB Member

«ControlNumber»

*XI. Sample HIPPA APPROVAL LETTER
(Expedited)*

DATE

«PIFirstName» «PIMiddleName» «PILastName», «Degree»
«Department»
Meharry Medical College
Nashville, TN 37208

RE: «Title» («Sponsor» «SponsorNumber»)

Dear «Salutation» «PILastName»:

The Institutional Review Board (IRB) approved your HIPAA authorization for the project above by expedited review. **Please use the enclosed HIPAA authorization with the IRB stamp as the original for all copies of the authorization.**

This approval is with the understanding that the use and disclosure of protected health information is consistent with the protocol and consent form. This approval is also with the understanding that the description of individuals, position of individuals, and institutions with whom protected health information will be shared is accurate. No additional use or disclosure of protected health information will be permitted without prior IRB approval. **The authorization does not have an expiration date and only needs to be re-submitted if there are changes in: 1) the type of protected health information collected; 2) the use of the protected health information or; 3) the disclosure of protected health information.**

If you have any questions regarding this please feel free to contact me or Cynthia Weaver at 6735.

Sincerely,

«PrimaryReviewer»
IRB Member

«ControlNumber»

XII. Sample HIPPA WAIVER FORM

REQUEST FOR WAIVER OF AUTHORIZATION***

IRB Protocol # _____

Title _____

1. The use or disclosure of Protected Health Information (PHI)* involves no more than a minimal risk to the privacy of individuals. Explain why? Include a detailed list of the PHI to be collected and a list of the source(s) of the PHI.

2. Describe the plan to protect identifiers and indicate where PHI will be stored and who will have access (researchers must list all of the entities that might have access to the study's PHI such as IRB, Meharry Medical College/Metro General Hospital representatives, sponsors, FDA, data safety monitoring boards and any others given authority by law);

3. All identifiers collected during the study will be destroyed at the earliest opportunity consistent with the conduct of research, which is: (describe the earliest opportunity below).

Please describe the procedure to be used to destroy all the data collected during the study (electronically, paper, audio/video, photography, other). OR

Alternatively, the identifiers collected during the study will not be destroyed because: (explain below).

4. The research could not practicably be conducted without the waiver because (explain below).

* Name, Address, Dates Directly Related to an Individual, Telephone/Fax Number, E-mail/Internet Protocol or Web URL Address, Social Security Number, Medical Record or Health Plan Number, Account Number, Certificate of License Number, Photographic Images, Vehicle Identifiers, Devise Identifiers, Biometric Identifiers, Any Other Unique Code

5. The research could not practicably be conducted without access to and use of the PHI because (explain below).

6. The HIPAA regulation requires reasonable efforts to limit protected health information to the minimum necessary to accomplish the intended purpose of the use, disclosure or request. Please note that researchers are also **accountable** for any PHI released under a waiver. Explain why PHI obtained for this study is/are the minimum information needed to meet the research objectives.

This form requests a waiver of authorization to use and disclose protected health information for research purposes. This waiver is contingent upon IRB review and approval and no protected health information may be assessed until this request for a waiver has been approved or you have obtained authorization from the research subject.

The information listed in the waiver request is accurate and all research staff** will comply with the HIPAA regulations and the waiver criteria.

I assure that the information I obtain as part of this research (including protected health information) will not be reused or disclosed to any other person or entity other than those listed on this form, except as required by law. If at any time I want to reuse this information for other purposes or disclose the information to other individuals or entity I will seek approval by the IRB.

Principal Investigator Signature

Name Typed

Date

**Note: Research staff is defined as ALL study personnel (including PI) that is involved in the research.

***HIPAA Regulations allow IRBs to waive use of authorization form if all of the criteria listed above are met.

XIII. Sample HIPPA WAIVER LETTER

DATE

«PIFirstName»«PIMiddleName» «PILastName», «Degree»
«Department»
Meharry Medical College
Nashville, TN 37208

RE: «Title» («Sponsor» «SponsorNumber»)

Dear «Salutation» «PILastName»:

The Institutional Review Board (IRB) approved your waiver of HIPAA authorization for the project above by expedited review. **Enclosed is a copy of the waiver of HIPAA authorization with the IRB stamp for your records.**

This approval is with the understanding that the use and disclosure of protected health information is consistent with the protocol and consent form. This approval is also with the understanding that the description of individuals, position of individuals, and institutions with whom protected health information will be shared is accurate. **No additional use or disclosure of protected health information will be permitted without prior IRB approval.** The waiver of authorization does not have an expiration date and only needs to be re-submitted if there are changes in: 1) the type of protected health information collected; 2) the use of the protected health information or; 3) the disclosure of protected health information. As the study proceeds, the committee may request additional information concerning the stipulations of this waiver to verify compliance.

If you have any questions regarding this please feel free to contact the IRB Office at 6735.

Sincerely,

«PrimaryReviewer»
IRB Member

«ControlNumber»

XIV. Sample Approval Sheet

To the School of Graduate Studies and Research: Æ Line 9

I am submitting herewith a thesis written by (name as it appears on the title page) entitled (complete title as it appears on the title page). I have examined the final copy of this thesis for form and content and recommend that it be accepted in partial fulfillment of the requirements for the degree of Master of Science in Public Health in the Division of Public Health Practice.

Director MSPH Program

We have read this thesis and
Recommend its acceptance:

Chair

Accepted for the Graduate School

Dean, School of Graduate Studies and
Research

Sample Approval Sheet

XV. Sample Title Page

FULL TITLE OF THESIS Æ Line 13

A Thesis Æ Line 24

Presented for the Æ Line 26

Master of Science and Public Health Æ Line 28

Degree Æ Line 30

Meharry Medical College Æ Line 32

(Name as it appears on school records) Æ Line 44

(Month and year of commencement) Æ Line 46

Sample Title Page

XVI. Sample Copyright Page

Copyright © 2006 by Lauren McCullough
All rights Reserved

Æ Line 20

Sample Copyright Page

XVII. Sample Dedication Page

DEDICATION

This thesis is dedicated to my parents
friends and family
who have given me invaluable educational opportunities

Sample Dedication Page

XVIII. Sample Acknowledgements

ACKNOWLEDGEMENTS

I would like to thank my major professor, Dr. Jack Watson, for his guidance and patience. I would also like to thank the other committee members, Dr. Joe Perona and Dr. Fred Weber for their comments and assistance over the past two years. I would like to express my thanks to my parents for encouragement and optimism. They encouraged me and reminded me of my goals. I would like to thank all the members of my family in Atlanta, Georgia.

Sample Acknowledgements

XIX. Sample Abstract

ABSTRACT Æ Line 13

There is a lack of information on whether brief nutrition education can succeed in improving longer-term dietary patterns in disadvantaged populations with HIV/AIDS. In the SMART/EST II Women's Project 466 disadvantaged women with HIV/AIDS were randomized to one of four groups and received a two-phase training consisting of a coping skills/stress management and nutrition education provided either in a group or individually. At baseline the majority of participants had excessive fat and sugar consumption and suboptimal intakes of vegetables, fruits, calcium-rich foods and whole grains. Dietary patterns for all participants improved after the nutrition intervention primarily due to decreases in high fat and high sugar foods such as soda and fried foods and were still significantly better 18 months later. There were only short-term differences in improvements between the four groups. These findings support the value of even brief nutrition education for disadvantaged women living with HIV/AIDS.

Sample Abstract

XX. Sample Table of Contents

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XXIII. Sample List of Abbreviations

LIST OF ABBREVIATIONS

Breast Cancer Walking Study.....	BCWS
Walking Management	WM
Band of Support	BS
Selected Essays	SE

Sample List of Abbreviations

XXIV. Sample List of References (First Page)

LIST OF REFERENCES

Æ Line 13

- [1] Abbott RA, Cox M, Markus H, Tomkins A. Diet, body size and micronutrient status in Parkinson's disease. *Eur J Clin Nutr* 46:879-84, 1992.
- [2] Azen SP, Qian D, Mack W, et al. Effect of supplementary antioxidant vitamin intake on carotid arterial wall intima-media thickness in a controlled clinical trial of cholesterol lowering. *Circulation* 94;10:2369-72, 1996.
- [3] Bhat KS. Nutritional status of thiamine, riboflavin and pyridoxine in cataract patients. *Nutr Rep Int* 363:685-92, 1987.

Sample List of References (First Page)

XXV. Sample Vita

VITA Æ Line 13

Vernon K. Smith was born in Harvey, Missouri on April 18, 1952. He graduated from Thornton High School in June, 1970. After two years of military service, he entered Harvey Community College and later transferred to Rust College where he received his Bachelor of Science degree in 1972. He received the Master of Science in Education degree from Jackson State University in 1974. He then became a teacher of mathematics at Hernando High School, Hernando, Mississippi from 1974 to 1980. In 1980, he became a teacher of mathematics in the Jackson Public School System and later, in 1985, an instructor in mathematics at Hinds Community College. He was a John Hay Fellow at Williams College, Williamstown, Massachusetts, during the summer of 1972.

He has been awarded grants from the National Science Foundation in 1981 and 1982 for programs aimed at improving the performance of secondary school students in mathematics. In 1988, he served as a reader of proposals for the National Science Foundation. He is the author of several articles, which have appeared in the *Mathematics Teacher*.

He married the former Elizabeth Joyce Gray in 1974, and they are the parents of two sons and a daughter. He and his family reside at 2902 Marshall Street in Holly Springs, Mississippi.

Sample Vita

XXVI. Sample Appendix (Separation page)

APPENDIX Æ Line 20

Sample Appendix (Separation page)

**MEHARRY MEDICAL COLLEGE
ANNOUNCEMENT**

Meharry Medical College
School of Graduate Studies & Research

Master's Thesis Defense

Abstract

The Effects of Nutritional Education on Longer-Term Dietary Patterns in Disadvantaged Populations with HIV/AIDS.

by

Joy M. Scott

There is a lack of information on whether brief nutrition education can succeed in improving longer-term dietary patterns in disadvantaged populations with HIV/AIDS. In the SMART/EST II Women's Project 466 disadvantaged women with HIV/AIDS were randomized to one of four groups and received a two-phase training consisting of a coping skills/stress management and nutrition education provided either in a group or individually. At baseline the majority of participants had excessive fat and sugar consumption and suboptimal intakes of vegetables, fruits, calcium-rich foods and whole grains. Dietary patterns for all participants improved after the nutrition intervention primarily due to decreases in high fat and high sugar foods such as soda and fried foods and were still significantly better 18 months later. There were only short-term differences in improvements between the four groups. These findings support the value of even brief nutrition education for disadvantaged women living with HIV/AIDS.

Date: November 23, 2004

Time: 10:30 a.m.

Place: Utmost Bound

Department: SOGSR/DPHP

Chairperson: Dr. Timothy Johnson

MSPH Thesis Defense Application Form
SCHOOL OF GRADUATE STUDIES AND RESEARCH
MEHARRY MEDICAL COLLEGE

Preparation to Defend

TO: The School of Graduate Studies and Research DATE: _____

FROM: _____

(Department)

Print/Type (Student)

Is submitting a thesis entitled:

(Full Title of Thesis)

****Please attach abstract and chapters 1-5 of thesis to this form****

In preparation to defend on:

(Date of defense)

(Location and Time)

For receipt of a Master of Science in Public Health

on:

(Date of Graduation)

The following Student and Thesis Committee members agree that _____ is ready to publicly defend thesis. Print/Type (Student)

(Signature of Student)

(Date)

(Signature of Chairperson)

(Date)

(Signature of Thesis Committee Member)

(Date)

(Signature of Thesis Committee Member)

(Date)

(Date) *II. Informed Consent Form*
Meharry Medical College

Informed Consent to Participate in Research

Title: Title of protocol.

Principal Investigator: Include name of P.I. and other investigators as appropriate.

Introduction/Background/Purpose: (Required in all consent forms) May be one or more sections; modify heading(s) as appropriate.

Federal Regulation: "...The following information shall be provided to each subject: (1) a statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation...." [45 CFR 46.116(a)(1) and for research subject to FDA regulation 21 CFR 50.25(a)(1)] When appropriate, the consent form should also state "the approximate number of subjects involved in the study. [45 CFR 46.116(b)(5) and 21 CFR 50.24(b)(5)]

This part of the consent form must include:

- A statement that potential subjects are being asked to volunteer for a research study
- An explanation of why the subject is being asked to volunteer.
- A clear explanation of the purpose of the research.
- The expected duration of the subject's total participation, and
- The approximate number of patients to be enrolled in the study and elsewhere. (Not required unless the number of subjects is material to the subject's decision to participate; e.g., small sample size might compromise confidentiality.)

Procedures: (Required in all consent forms)

Federal Regulation: "...The following information shall be provided to each subject: (1) "...a description of the procedures to be followed, and identification of any procedures which are experimental." [45CFR 46.116(a)(1) and 21 CFR 50.24(a)(1)]

This section must include:

- A detailed description and explanation of the procedures that will be performed on the subject, e.g. filling out questionnaires, being interviewed, being audio or videotaped, engaging in role playing, performing computerized experiments, etc.
- A full explanation of all responsibilities and expectations of the subject. Be sure to communicate the following:
 - All of the different people with whom the subject will interact with, if applicable.
 - Where the research will be done.
 - When the research will be done.
 - How often the procedures will be performed.
 - How much of the subject's time will be involved in each session, and in total
- A statement of how the subject will be compensated for their time and expenses (i.e., cash, coupons, t-shirt, etc.). If none, explain there is no compensation.

Benefits: (Required in all consent forms)

Federal Regulation: "...The following information shall be provided to each subject: (3) a description of any benefits to the subject or to others which may reasonably be expected from the research." [45 CFR 46.116(a)(3) and 21 CFR 50.25(a)(3)]

This section should include a statement that there may be no benefit to the subject. Any benefits to the subject or others that can be expected should be described, but in a way that is not coercive, enticing, or self-serving. Benefit to society is appropriate. Do not refer to financial compensation in this section.

Costs of Treatment: (Required in all consent forms)

A description of costs (research and standard care) and who is responsible for payment.

Risks: (Required in all consent forms)

Federal Regulation: "...The following information shall be provided to each subject: (2) a description of any reasonably foreseeable risks or discomforts to the subject." [45 CFR 46.116(a)(2) and, 21 CFR 50.25(a)(2)].

Alternative Procedures: (Required in all consent forms).

A disclosure of any alternative procedures which might be advantageous to the subject.

Compensation: (Required in all consent forms)

(This section is required for projects that involve greater than minimal risk).

Federal Regulation: "...The following information shall be provided to each subject: (8) an explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research related injury to the subject." [45 CFR 46.116(a)(7) and 50CFR 21.25(a)(7)]

Confidentiality: (Required in all consent forms)

Federal Regulation: "...The following information shall be provided to each subject: (5) a statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained." [(45 CFR 46.116(a)(5)]

The following is acceptable wording for this statement; it should be modified as appropriate:
We will keep your records private to the extent allowed by law. We will use [a study number, your initials*] rather than your name on study records where we can. Your name and other facts that might point to you will not appear when we present this study or publish its results.

*Include or omit as appropriate.

Subject Rights: (Required in all consent forms)

Federal Regulation: "A copy [of the consent form] shall be given to the person signing the form." [45 CFR 46.117(a) and 21 CFR 50.27(a)]

Voluntary Participation and withdrawal is incorporated into the "Subject Rights" section. Federal Regulation: "...The following information shall be provided to each subject: (8) a statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled. [45 CFR 46.116(a)(8) and 21 CFR 50.25(a)(8)]

PLEASE PROOF READ!

Look for the following:

- Spelling, typographical and grammatical errors
- Consent forms should never be written in first person. ("I am being asked to be in a research study...."). The committee prefers 2nd grammatical person when the person signing the consent form is always the study subject. Be sure the document consistently refers to the potential study subject as "you." If the study is such that consent will be obtained from someone other than the actual subject (e.g., a parent, next of kin, or legal guardian) the consent form should be written in the 3rd person (e.g., "Participants in this study will undergo the following tests and procedures.") This is especially true if the consent form sometimes will be given to the subject, and sometimes to a parent or guardian. Avoid the following style: "If you (your child) agree/agrees to participate in this study you/he/she will have the following tests and procedures performed."
- Technical/advanced language – When writing the consent form, aim for an 8th grade level. Most word processors include utilities in the "Tools" menu to analyze the reading level of text. Use these tools!
- Write in short declarative sentences. Use simple words of fewer than three syllables whenever possible.
- Avoid long complex sentences.
- Avoid using technical terms as much as possible. If you must use technical terms, explain what they mean in lay language.
- Include a version date and page numbers.
- Avoid using "You understand..." It implies the subject understands more than he/she may comprehend. It can be interpreted as suggestive and can constitute coercive influence over a subject.

III. Sample Informed Consent Form
INFORMED CONSENT TO PARTICIPATE IN RESEARCH

Principal Investigator:

Telephone No.:

Meharry Medical College

Dept.:

Title of Project:

You are being asked to volunteer as a participant in a research study. This form is designed to provide you with information about this study. (THIS STATEMENT IS REQUIRED)

PURPOSE: Explain the purposes of the research and the expected duration of the subject's participation.

PROCEDURES: Describe the procedures to be followed, expected duration, and identify any procedures which are investigational.

BENEFITS: Describe any benefits to the subject or to others.

COSTS OF TREATMENT: Describe any costs incurred by the study and who is responsible for payment.

RISKS: Describe any foreseeable risks or discomforts, including psychological, legal, or social risks.

ALTERNATIVE PROCEDURES: Describe alternative procedures which might be advantageous to the subject (if applicable).

COMPENSATION: (This section is required for projects that involve greater than minimal risk).

You should report any injury or illness, which you believe to be related to this research project to Jane Doe, M.D., Principal Investigator at 327-1234, or James L. Potts, M.D., Chair of the Meharry Institutional Review Board, at 327-6735. Medical treatment for injury of illness resulting from the research procedures is available at Metropolitan Nashville General Hospital. Payment for this medical treatment is your responsibility. Meharry Medical College, the research sponsor, and their agents and employees are not responsible for the payment of medical care or for compensation of any expenses associated with research-related illness or injury.

The above "Compensation" statement does not limit your legal rights. You do not waive any legal rights by signing this form.

CONFIDENTIALITY: Describe how data will be kept confidential, who will have access to data (include organizations that will have access, i.e. FDA), where data will be stored, and how long data will be stored.

SUBJECT RIGHTS: Any questions you have involving the research and your rights may be addressed to [insert Principal Investigator's name] at _____ or James L. Potts, M.D., chair of the Meharry Institutional Review Board, at 327-6735. Your participation in this study is

Voluntary and you are free to withdraw at anytime without penalty or loss of benefits that you are otherwise entitled to. You will be given a copy of this form to keep.

Signature of Participant

Date

Signature of Witness

Date

Signature of person who obtains consent

Date

Insert a space at the bottom of each page of the consent form for the subjects initials (Subject Initials ____), if the consent form is longer than one page. Number all pages; the total number of pages must be on each page (e.g. Page 1 of 4)

*IV. Sample IRB Approval Letter
Full Board Review*

Date

«PIFirstName» «PIMiddleName» «PILastName», «Degree»
Division of Public Health Practice
Meharry Medical College
Nashville, TN 37208

RE: FINAL IRB APPROVAL of «Title» («Sponsor» «SponsorNumber»)

Dear «Salutation» «PILastName»:

The Institutional Review Board approved the corrections and clarifications to the protocol and the consent form dated «CnsntFrmDate» for the project above. **Please use the enclosed consent form with the IRB stamp as the original for all copies of the consent form.**

The project and consent form were approved at the IRB's meeting on «MeetingDate»; this approval period ends on «Next_ExpDate» with the understanding that any changes in the protocol or consent form which affect human subjects (number of subjects, dosages, frequency of visits, etc) must be approved by the IRB before being implemented. During the course of the study, any local serious events, whether anticipated or unanticipated, must be reported to the IRB within 48 hours. Any serious adverse events that occur at other sites must be reported to the IRB within five working days. In the event that you or the sponsor closes or suspends the study, the IRB must be notified within five working days.

In «SndMatMY» you will be sent the material required for this project's periodic review, and the IRB will require a progress report at that time.

If you have any questions, please call me or Cynthia Weaver in the Office of Grants Management at 6735.

Sincerely yours,

Name of Chair
Chair

«ControlNumber»

V. Sample IRB Approval Letter
Expedited Review

Date

«PIFirstName» «PIMiddleName» «PILastName», «Degree»
Division of Public Health Practice
Meharry Medical College
Nashville, TN 37208

RE: «Title» («Sponsor» «SponsorNumber»)

Dear «Salutation» «PILastName»:

The Institutional Review Board (IRB) approved your proposal and consent form dated «CnsntFrmDate» for the project above by expedited review based on 45 CFR 46.110 category based on category. **Please use the enclosed consent form with the IRB stamp as the original for all copies of the consent form.**

The approval period ends on «Next_ExpDate» with the understanding that any changes in the protocol or consent form which affect human subjects must be approved by the IRB before being implemented. During the course of the study, any local serious adverse events, whether anticipated or unanticipated, must be reported to the IRB within 48 hours. Any serious adverse events that occur at other sites must be reported within five working days. In the event that you or the sponsor closes or suspends the study, the IRB must be notified within five working days.

In «SndMatMY» you will receive the material required for the project's continuing review and approval.

The IRB will need information regarding the implementation of the project and the results to date.

If you have any questions regarding this please feel free to contact me or the IRB office at 6735.

Sincerely,

«PrimaryReviewer»
IRB Member

«ControlNumber»

VI. Sample IRB Approval Letter
Exempt Review

Date

«PIFirstName» «PIMiddleName» «PILastName», «Degree»
Division of Public Health Practice
Meharry Medical College
Nashville, TN 37208

RE: «Title» («Sponsor» «SponsorNumber»)

Dear «Salutation» «PILastName»:

The Institutional Review Board has determined that the project above is exempt based on [i.e., category 45 CFR 46.101(b) (4) of the federal regulations concerning the use of existing records, data, pathological specimens or diagnostic specimens when the information is recorded by the investigator in such a manner that subjects cannot be identified.] No consent form is needed.

If you have any questions regarding this please feel free to contact me or Cynthia Weaver at 6735.

Sincerely,

«PrimaryReviewer»
IRB Member

«ControlNumber»

VII. Sample IRB Approval Letter
Exempt Review

Date

«PI FirstName» «PI MiddleName» «PI LastName», «Degree»
Division of Public Health Practice
Meharry Medical College
Nashville, TN 37208

RE: «Title» («Sponsor» «SponsorNumber»)

Dear «Salutation» «PI LastName»:

The Institutional Review Board has determined that the project above is exempt based on [i.e., category 45 CFR 46.101(b) (4) of the federal regulations concerning the use of existing records, data, pathological specimens or diagnostic specimens when the information is recorded by the investigator in such a manner that subjects cannot be identified.] No consent form is needed.

If you have any questions regarding this please feel free to contact me or Cynthia Weaver at 6735.

Sincerely,

«PrimaryReviewer»
IRB Member

«ControlNumber»

*VIII. INSERTION OF HUMAN SUBJECT REVIEW FORM (HSRF)
FOR FULL BOARD AND EXPEDITED REVIEW (DOC)*

INSERTION OF EXEMPT FORM (DOC)

Meharry Medical College

AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION FOR RESEARCH PURPOSES

{Project Title}

{Principal Investigator} – Principal Investigator

The privacy law, Health Insurance Portability & Accountability Act (HIPAA), protects your individually identifiable health information (protected health information). The privacy law requires you to sign an authorization (or agreement) in order for researchers to be able to use or disclose your protected health information for research purposes in the study entitled [*Insert title of study*].

By signing this, you authorize [*name of researcher*] and his/her research staff to use and disclose your protected health information for the purposes described below. You also permit your doctors and other health care providers to disclose your protected health information for the purposes described below.

Your protected health information that may be used and disclosed includes:

- [*List all of the protected health information* to be collected for this protocol/study such as demographic information, results of physical exams, blood tests, X-rays, and other diagnostic and medical procedures as well as medical history*]

Your protected health information will be used for:

- [*Provide a brief description of each research purpose or paste information from purpose section in the consent form; indicate that one reason to share the information is to be able to conduct the research, another reason is to ensure that the research meets legal, institutional or accreditation requirements*]

The Researchers may use and share your health information with:

- The Meharry Medical College's Institutional Review Board/Office of Research Support Services
- Government representatives, when required by law
- [*List any collaborators, outside laboratories, etc.*]
- [*If applicable – list the sponsor's name*]
- [*List any other groups with whom the information may be shared*]

* Name, Address, Dates Directly Related to an Individual, Telephone/Fax Number, E-mail/Internet Protocol or Web URL Address, Social Security Number, Medical Record or Health Plan Number, Account Number, Certificate of License Number, Photographic Images, Vehicle Identifiers, Device Identifiers, Biometric Identifiers, Any Other Unique Code

Once your health information has been disclosed to anyone outside of this study, the information may no longer be protected under this authorization.

The researchers [*and list sponsor's name if applicable*] agree to protect your health information by using and disclosing it only as permitted by you in this Authorization and as directed by state and federal law

You do not have to sign this Authorization. If you decide not to sign the Authorization:

- It will not affect your treatment, payment or enrollment in any health plans or affect your eligibility for benefits.
- You may not be allowed to participate in the research study.

After signing the Authorization, you can change your mind and:

- Not let the researcher disclose or use your protected health information (revoke the Authorization).
- **If you revoke the Authorization, you must send a written letter to: [*name and contact information*]** to inform him/her of your decision.
- If you revoke this Authorization your protected health information may still be used and disclosed should you have an adverse event (a bad effect).
- If you change your mind and withdraw the authorization, you may not be allowed to continue to participate in the study.

Note: You may not revoke authorization of the use and disclosure of the protected health information that had already been collected prior to revoking the authorization.

You will not be allowed to review the information collected for the research until after the study is completed. When the study is over, you will have the right to access the information again.

This Authorization does not have an expiration date.

If you would like a copy of the Privacy Notice, you may request one. If you have any questions or concerns about your privacy rights, you should contact the Meharry Medical College Privacy Officer at Ph: (615) 327-6102.

You are the subject or you are authorized to act on behalf of the subject. You have read this information, and you will receive a copy of this form after it is signed.

Signature of research subject or *research
subject's legal representative

Date

Printed name of research subject or
*research subject's legal representative

Representative's relationship to
research subject

*Please explain Representative's Relationship to Subject and include a
description of Representative's Authority to act on behalf of Subject:

X. Sample HIPPA APPROVAL LETTER
(Full Board)

DATE

«PIFirstName» «PIMiddleName» «PILastName», «Degree»
«Department»
Meharry Medical College
Nashville, TN 37208

RE: «Title» («Sponsor» «SponsorNumber»)

Dear «Salutation» «PILastName»:

The Institutional Review Board (IRB) approved the HIPAA authorization for the project above at its meeting on «MeetingDate». **Please use the enclosed HIPAA authorization with the IRB stamp as the original for all copies of the authorization.**

This approval is with the understanding that the use and disclosure of protected health information is consistent with the protocol and consent form. This approval is also with the understanding that the description of individuals, position of individuals, and institutions with whom protected health information will be shared is accurate. No additional use or disclosure of protected health information will be permitted without prior IRB approval. **The authorization does not have an expiration date and only needs to be re-submitted if there are changes in: 1) the type of protected health information collected; 2) the use of the protected health information or; 3) the disclosure of protected health information.**

If you have any questions regarding this please feel free to contact the IRB Office at 6735.

Sincerely,

Primary Reviewer
IRB Member

«ControlNumber»

*XI. Sample HIPPA APPROVAL LETTER
(Expedited)*

DATE

«PIFirstName» «PIMiddleName» «PILastName», «Degree»
«Department»
Meharry Medical College
Nashville, TN 37208

RE: «Title» («Sponsor» «SponsorNumber»)

Dear «Salutation» «PILastName»:

The Institutional Review Board (IRB) approved your HIPAA authorization for the project above by expedited review. **Please use the enclosed HIPAA authorization with the IRB stamp as the original for all copies of the authorization.**

This approval is with the understanding that the use and disclosure of protected health information is consistent with the protocol and consent form. This approval is also with the understanding that the description of individuals, position of individuals, and institutions with whom protected health information will be shared is accurate. No additional use or disclosure of protected health information will be permitted without prior IRB approval. **The authorization does not have an expiration date and only needs to be re-submitted if there are changes in: 1) the type of protected health information collected; 2) the use of the protected health information or; 3) the disclosure of protected health information.**

If you have any questions regarding this please feel free to contact me or Cynthia Weaver at 6735.

Sincerely,

«PrimaryReviewer»
IRB Member

«ControlNumber»

XII. Sample HIPPA WAIVER FORM

REQUEST FOR WAIVER OF AUTHORIZATION***

IRB Protocol # _____

Title _____

1. The use or disclosure of Protected Health Information (PHI)* involves no more than a minimal risk to the privacy of individuals. Explain why? Include a detailed list of the PHI to be collected and a list of the source(s) of the PHI.

2. Describe the plan to protect identifiers and indicate where PHI will be stored and who will have access (researchers must list all of the entities that might have access to the study's PHI such as IRB, Meharry Medical College/Metro General Hospital representatives, sponsors, FDA, data safety monitoring boards and any others given authority by law);

3. All identifiers collected during the study will be destroyed at the earliest opportunity consistent with the conduct of research, which is: (describe the earliest opportunity below).

Please describe the procedure to be used to destroy all the data collected during the study (electronically, paper, audio/video, photography, other). OR

Alternatively, the identifiers collected during the study will not be destroyed because: (explain below).

4. The research could not practicably be conducted without the waiver because (explain below).

* Name, Address, Dates Directly Related to an Individual, Telephone/Fax Number, E-mail/Internet Protocol or Web URL Address, Social Security Number, Medical Record or Health Plan Number, Account Number, Certificate of License Number, Photographic Images, Vehicle Identifiers, Devise Identifiers, Biometric Identifiers, Any Other Unique Code

5. The research could not practicably be conducted without access to and use of the PHI because (explain below).

6. The HIPAA regulation requires reasonable efforts to limit protected health information to the minimum necessary to accomplish the intended purpose of the use, disclosure or request. Please note that researchers are also **accountable** for any PHI released under a waiver. Explain why PHI obtained for this study is/are the minimum information needed to meet the research objectives.

This form requests a waiver of authorization to use and disclose protected health information for research purposes. This waiver is contingent upon IRB review and approval and no protected health information may be assessed until this request for a waiver has been approved or you have obtained authorization from the research subject.

The information listed in the waiver request is accurate and all research staff** will comply with the HIPAA regulations and the waiver criteria.

I assure that the information I obtain as part of this research (including protected health information) will not be reused or disclosed to any other person or entity other than those listed on this form, except as required by law. If at any time I want to reuse this information for other purposes or disclose the information to other individuals or entity I will seek approval by the IRB.

Principal Investigator Signature

Name Typed

Date

**Note: Research staff is defined as ALL study personnel (including PI) that is involved in the research.

***HIPAA Regulations allow IRBs to waive use of authorization form if all of the criteria listed above are met.

XIII. Sample HIPPA WAIVER LETTER

DATE

«PIFirstName»«PIMiddleName» «PILastName», «Degree»
«Department»
Meharry Medical College
Nashville, TN 37208

RE: «Title» («Sponsor» «SponsorNumber»)

Dear «Salutation» «PILastName»:

The Institutional Review Board (IRB) approved your waiver of HIPAA authorization for the project above by expedited review. **Enclosed is a copy of the waiver of HIPAA authorization with the IRB stamp for your records.**

This approval is with the understanding that the use and disclosure of protected health information is consistent with the protocol and consent form. This approval is also with the understanding that the description of individuals, position of individuals, and institutions with whom protected health information will be shared is accurate. **No additional use or disclosure of protected health information will be permitted without prior IRB approval.** The waiver of authorization does not have an expiration date and only needs to be re-submitted if there are changes in: 1) the type of protected health information collected; 2) the use of the protected health information or; 3) the disclosure of protected health information. As the study proceeds, the committee may request additional information concerning the stipulations of this waiver to verify compliance.

If you have any questions regarding this please feel free to contact the IRB Office at 6735.

Sincerely,

«PrimaryReviewer»
IRB Member

«ControlNumber»

XIV. Sample Approval Sheet

To the School of Graduate Studies and Research: Æ Line 9

I am submitting herewith a thesis written by (name as it appears on the title page) entitled (complete title as it appears on the title page). I have examined the final copy of this thesis for form and content and recommend that it be accepted in partial fulfillment of the requirements for the degree of Master of Science in Public Health in the Division of Public Health Practice.

Director MSPH Program

We have read this thesis and
Recommend its acceptance:

Chair

Accepted for the Graduate School

Dean, School of Graduate Studies and
Research

Sample Approval Sheet

XV. Sample Title Page

FULL TITLE OF THESIS Æ Line 13

A Thesis Æ Line 24

Presented for the Æ Line 26

Master of Science and Public Health Æ Line 28

Degree Æ Line 30

Meharry Medical College Æ Line 32

(Name as it appears on school records) Æ Line 44

(Month and year of commencement) Æ Line 46

Sample Title Page

XVI. Sample Copyright Page

Copyright © 2006 by Lauren McCullough
All rights Reserved

Æ Line 20

Sample Copyright Page

XVII. Sample Dedication Page

DEDICATION

This thesis is dedicated to my parents
friends and family
who have given me invaluable educational opportunities

Sample Dedication Page

XVIII. Sample Acknowledgements

ACKNOWLEDGEMENTS

I would like to thank my major professor, Dr. Jack Watson, for his guidance and patience. I would also like to thank the other committee members, Dr. Joe Perona and Dr. Fred Weber for their comments and assistance over the past two years. I would like to express my thanks to my parents for encouragement and optimism. They encouraged me and reminded me of my goals. I would like to thank all the members of my family in Atlanta, Georgia.

Sample Acknowledgements

XIX. Sample Abstract

ABSTRACT Æ Line 13

There is a lack of information on whether brief nutrition education can succeed in improving longer-term dietary patterns in disadvantaged populations with HIV/AIDS. In the SMART/EST II Women's Project 466 disadvantaged women with HIV/AIDS were randomized to one of four groups and received a two-phase training consisting of a coping skills/stress management and nutrition education provided either in a group or individually. At baseline the majority of participants had excessive fat and sugar consumption and suboptimal intakes of vegetables, fruits, calcium-rich foods and whole grains. Dietary patterns for all participants improved after the nutrition intervention primarily due to decreases in high fat and high sugar foods such as soda and fried foods and were still significantly better 18 months later. There were only short-term differences in improvements between the four groups. These findings support the value of even brief nutrition education for disadvantaged women living with HIV/AIDS.

Sample Abstract

XX. Sample Table of Contents

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XXIII. Sample List of Abbreviations

LIST OF ABBREVIATIONS

Breast Cancer Walking Study.....	BCWS
Walking Management	WM
Band of Support	BS
Selected Essays	SE

Sample List of Abbreviations

XXIV. Sample List of References (First Page)

LIST OF REFERENCES

Æ Line 13

- [1] Abbott RA, Cox M, Markus H, Tomkins A. Diet, body size and micronutrient status in Parkinson's disease. *Eur J Clin Nutr* 46:879-84, 1992.
- [2] Azen SP, Qian D, Mack W, et al. Effect of supplementary antioxidant vitamin intake on carotid arterial wall intima-media thickness in a controlled clinical trial of cholesterol lowering. *Circulation* 94;10:2369-72, 1996.
- [3] Bhat KS. Nutritional status of thiamine, riboflavin and pyridoxine in cataract patients. *Nutr Rep Int* 363:685-92, 1987.

Sample List of References (First Page)

XXV. Sample Vita

VITA Æ Line 13

Vernon K. Smith was born in Harvey, Missouri on April 18, 1952. He graduated from Thornton High School in June, 1970. After two years of military service, he entered Harvey Community College and later transferred to Rust College where he received his Bachelor of Science degree in 1972. He received the Master of Science in Education degree from Jackson State University in 1974. He then became a teacher of mathematics at Hernando High School, Hernando, Mississippi from 1974 to 1980. In 1980, he became a teacher of mathematics in the Jackson Public School System and later, in 1985, an instructor in mathematics at Hinds Community College. He was a John Hay Fellow at Williams College, Williamstown, Massachusetts, during the summer of 1972.

He has been awarded grants from the National Science Foundation in 1981 and 1982 for programs aimed at improving the performance of secondary school students in mathematics. In 1988, he served as a reader of proposals for the National Science Foundation. He is the author of several articles, which have appeared in the *Mathematics Teacher*.

He married the former Elizabeth Joyce Gray in 1974, and they are the parents of two sons and a daughter. He and his family reside at 2902 Marshall Street in Holly Springs, Mississippi.

Sample Vita

XXVI. Sample Appendix (Separation page)

APPENDIX Æ Line 20

Sample Appendix (Separation page)

**MEHARRY MEDICAL COLLEGE
ANNOUNCEMENT**

Meharry Medical College
School of Graduate Studies & Research

Master's Thesis Defense

Abstract

The Effects of Nutritional Education on Longer-Term Dietary Patterns in Disadvantaged Populations with HIV/AIDS.

by

Joy M. Scott

There is a lack of information on whether brief nutrition education can succeed in improving longer-term dietary patterns in disadvantaged populations with HIV/AIDS. In the SMART/EST II Women's Project 466 disadvantaged women with HIV/AIDS were randomized to one of four groups and received a two-phase training consisting of a coping skills/stress management and nutrition education provided either in a group or individually. At baseline the majority of participants had excessive fat and sugar consumption and suboptimal intakes of vegetables, fruits, calcium-rich foods and whole grains. Dietary patterns for all participants improved after the nutrition intervention primarily due to decreases in high fat and high sugar foods such as soda and fried foods and were still significantly better 18 months later. There were only short-term differences in improvements between the four groups. These findings support the value of even brief nutrition education for disadvantaged women living with HIV/AIDS.

Date: November 23, 2004

Time: 10:30 a.m.

Place: Utmost Bound

Department: SOGSR/DPHP

Chairperson: Dr. Timothy Johnson

MSPH Thesis Defense Application Form
SCHOOL OF GRADUATE STUDIES AND RESEARCH
MEHARRY MEDICAL COLLEGE

Preparation to Defend

TO: The School of Graduate Studies and Research DATE: _____

FROM: _____

(Department)

Print/Type (Student)

Is submitting a thesis entitled:

(Full Title of Thesis)

****Please attach abstract and chapters 1-5 of thesis to this form****

In preparation to defend on:

(Date of defense)

(Location and Time)

For receipt of a Master of Science in Public Health

on:

(Date of Graduation)

The following Student and Thesis Committee members agree that _____ is ready to publicly defend thesis. Print/Type (Student)

(Signature of Student)

(Date)

(Signature of Chairperson)

(Date)

(Signature of Thesis Committee Member)

(Date)

(Signature of Thesis Committee Member)

(Date)

