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St. Jude Graduate School of Biomedical Sciences

MS in Clinical Investigations

Thesis Handbook

St. Jude Children's Research Hospital

Graduate School of Biomedical Sciences

Table of Contents

SECTION I: OVERVIEW

The Master of Science in Clinical Investigations (MSCI) Program provides transformative education to create a cadre of health professionals adept at designing, conducting and reporting clinical investigations that further human health. The MSCI Program integrates traditional academic training and experiential learning and is designed to produce future leaders committed to bringing positive change to human health and wellness.

The thesis is the demonstration of the student's mastery of both a specific content area as well as the methodology necessary to make significant contributions to medical literature. It serves as the primary locus for translation of the knowledge, tools, and skills that students acquire through the program.

In the MSCI program, there are two options for the thesis – the *Completed Research Option* and the *Prospective Clinical Trial Option*. The sections below outline the differences and help guide selection of which option is more appropriate for the student's graduate work. Both options demonstrate the student's exercise in research, allow a substantial contribution to the field, and provide the opportunity to work closely with the student's thesis committee.

SECTION II: COMPLETED RESEARCH OPTION

Description

The Completed Research Option will represent a completed research project that demonstrates an in-depth understanding of the subject matter, development of a hypothesis, collection/analysis of data to test the hypothesis and ability to place the results within the context of previously published literature. Broadly, the final thesis will consist of an introduction outlining the importance of the specific research, a summary of existing literature, statement of a scientific hypothesis, description of methods used, including analytic methodology, results, and a discussion that places the thesis findings in the context of current knowledge with recommendations for future research and potential recommended changes in clinical management, measurement, or other interventions. Because this Thesis option requires collection and analysis of data, existing data or publicly available datasets are often used.

In general, the student and their identified mentors should jointly identify and discuss plans for completion of the Thesis. The student should select a topic that can sustain the student's interest over time. The project should not be over-ambitious requiring substantially longer than the second year of the program. Close communication with mentors, especially in the early months of the second year, should guide the student in the identification of an interesting, feasible master's thesis.

Format

The *Completed Research Thesis* option will consist of the following chapters with approximate length provided. Additional chapters may be added when appropriate.

Chapter I: Introduction (7-10 pages)

The introduction includes a description of the problem that will be the focus of the project, with a justification of why it will be undertaken and why the reader should care. It describes the context of the problem explaining why the project is relevant and timely. The introduction mentions the key sections of the thesis.

Chapter II: Literature Review (5-8 pages)

Chapter II states the problem, and reviews relevant literature to describe the problem and justify the attention given to it. It contains review of relevant research literature addressing the nature of the problem(s), cause for action, models, policy, and strategies to improve outcomes related to the problem—in short, it provides the conceptual and scientific foundation for the proposed project.

Chapter III: Statement of the Hypothesis to be Tested (1 page)

Chapter III includes a brief statement of the hypothesis(es) to be tested.

Chapter IV: Methods (7-10 pages)

This chapter describes the approach or strategy for action to address the problem. It is based on logic and justification grounded in evidence. It includes a description of the project in explicit detail, including the definitions used, population(s) studied, data to be collected/used, data source and characteristics, data analysis methods, documentation of appropriate human subjects protection committee review and approval, if appropriate, and quality assurance procedures.

Chapter V: Results (10-15 pages)

The Results chapter describes the characteristics of the data studied and results of analyses. Tables and Figures are included to summarize and pictorially display the findings.

Chapter VI: Discussion (3-5 pages)
This chapter describes the findings and how they fit into the broader understanding of the problem being studied. Recommendations about the applications of the findings should be included, as should possible limitations of the thesis.

References
A complete list of APA formatted and cited material and key sources of insight.

Appendices
Additional relevant material may be included as appendices. If included, they must be cited in the thesis.

SECTION III: PROSPECTIVE CLINICAL TRIAL OPTION

Description

For the Prospective Clinical Trial, the student will write and submit a protocol for consideration as thesis work. The project should demonstrate the student's ability to apply the principles learned in the program's curriculum to their own research project.

The submitted Prospective Clinical Research Study should benefit from the advice of colleagues and experts in the field. It should include sufficient details to ensure a uniform and standardized approach to carrying out the study with good quality control.

A well-thought out and well-written protocol can be judged according to three main criteria:

1. Is it adequate to answer the research question(s), and achieve the study objective?
2. Is it feasible?
3. Does it provide enough detail that another investigator can undertake the study and arrive at comparable conclusions?

The protocol should outline the rationale for the study, its objective, the methodology used and how the data will be managed and analyzed. It should highlight how ethical issues have been considered, and, where appropriate, how inclusion across different age groups and gender issues are being addressed. If the protocol is an interventional trial (therapeutic or non-therapeutic), it should follow protocol guidelines available in the literature to standardize the approach and outline its contents (for example the SPIRIT Guidelines). If the Clinical Trial is planned to be conducted within a system with published guidelines, these can be followed. A copy or link to the system's guidelines should be included. For Clinical Trials proposed to be conducted at St. Jude Children's Research Hospital, specific templates can be located at: https://home.stjude.org/clinical-trials-administration/Pages/forms.aspx by clicking on "CTA Forms" in the Toolbox. There you will find templates for therapeutic and non-therapeutic protocols.

Format

The *Prospective Clinical Trial* will consist of the following sections with approximate page length provided. Additional information may be added when appropriate.

Project Title

The title should be descriptive and concise. It may need to be revised after completion of the writing of the protocol to reflect more closely the sense of the study.

Project Summary (1-2 pages)

The summary should be concise and should summarize all the elements of the protocol. It should stand on its own, and not refer the reader to points in the project description. A structured format is optimal.

Project Description that includes the following sections:

Rationale (5-7 pages)

This is equivalent to the introduction in a research paper. It puts the proposal in context. It should answer the question of why and what: why the research needs to be done and what will be its relevance. A brief description of the most relevant studies published on the subject should be provided to support the rationale for the study. This background materials should reflect an in-depth review of the relevant topic literature.

Objective(s) (1 page)
Specific objectives are statements of the research question(s). Objectives should be simple (not complex), specific (not vague), and stated in advance (not after the research is done). After statement of the primary objective, secondary objectives may be mentioned. You are advised to resist the temptation to put too many objectives or over-ambitious objectives that cannot be adequately achieved by the implementation of the protocol. Exploratory objectives can be considered but cost-considerations and time necessary to collect additional data or specimens should be justified.

Hypothesis(ses) (<1 page)
The hypothesis (ses) that support the primary objective(s) of the study should be stated.

Methodology (15-20 pages)
The methodology section must be thought out carefully and written in full detail. It is the most important part of the protocol. It should include information on the research design, the research subjects, interventions introduced, observations to be made and the sample size.

Research design: The choice of the design should be explained in relation to the study objectives.

Research subjects or participants: Depending on the type of the study, the following questions should be answered: What are the criteria for inclusion or selection? What are the criteria for exclusion? In intervention studies, how will subjects be allocated to index and comparison groups? What are the criteria for discontinuation?

Interventions: If an intervention is introduced, a description must be given of the drugs or devices to be used, and whether they are already commercially available, or in phases of experimentation. For drugs and devices that are commercially available, the protocol must state their proprietary names, manufacturer, chemical composition, dose and frequency of administration. For drugs and devices that are still in the experimental stage (or that are commercially available but are being used for a different indication or in a different mode of administration), additional information should be provided on available pre-clinical investigations in animals and/or results of studies already conducted on humans. In such cases, the approval of the drug regulatory agency in the country is generally needed before implementing the study.

Participant Management: Information should be provided about participants will be managed while on study. Specifically, how adverse events will be assessed and managed in the individual participant and development of new conditions such as pregnancy. Information should be provided about how and when adverse events will be reported to oversight bodies. Safety Monitoring Committees or Data, Safety Monitoring Boards should be described if applicable.

Observations: Information should be provided on the observations to be made, how they will be made, and how frequently will they be made. If the observation is made by a questionnaire, this should be appended to the protocol. Laboratory or other diagnostic and investigative procedures should be described. Surveys or other subjective assessment tools should be included. If standardized instruments are used, the validated population(s) should be named. A tabular schedule of evaluations should be developed.

For established health researchers, reference to appropriate published work is enough. For new or modified procedures, an adequate description is needed, with a justification for their use.

Data management and analysis (4-5 pages)

The protocol should provide information on how the data will be collected and managed, including data coding for computer analysis, monitoring and verification. If software packages are used, please include key features necessary to assess. The statistical methods used for the analysis of data should be clearly outlined. Key components include the definitions and measurement of outcomes, stopping rules based on safety, interim analysis (ses). If randomization techniques are employed, they should be described. The protocol should provide information and justification about sample size. The basis on which sample size is calculated should be explained in the methodology section of the protocol. Feasibility should also be included as well as recruitment /retention strategies and a time line for accrual should be proposed.

Ethical considerations (14 pages)

These apply to all types of health research. Your protocol must include a section addressing ethical considerations. This includes two components: The first is your plan for a written submission to the appropriate ethics review committee (IRB), together with a written form for informed consent, where appropriate. As appropriate assent considerations should be addressed.

A high-level summary of key information **(2 pages)** from your detailed full consent document.

A full consent document **(10 pages,** dependent on the complexity of the study**),** where appropriate, must be developed and attached to the protocol. It should be written in the prospective subjects' primary language. The consent form has two parts: a) a statement describing the study and the nature of the subject's involvement in it; and b) a certificate of consent attesting to the subject's consent. Both parts should be written in simple language so that the subject can easily understand the contents. The statement should, as appropriate, explain why the study is being done and why the subject has been asked to participate. It should describe, in sequence, what will happen in the course of the study, giving enough detail for the subject to gain a clear idea of what to expect. It should clarify whether or not the study procedures offer any benefits to the subject or to others, and explain the nature, likelihood and treatment of anticipated discomfort or adverse effects, including psychological and social risks, if any. Where relevant, the statement should include a comparison with risks posed by standard treatments or drugs. If the risks are unknown or a comparative risk cannot be given it should be so stated. Finally, the statement should indicate that the subject has the right to withdraw from the study at any time without, in any way, affecting her/his further medical care.

The second is a special section **(2 pages)** that address all possible ethical concerns. This should include your own assessment and brief description of any issues that could be raised about the methodology, including the research design, selection of subjects, the interventions introduced and the observations to be made. The use of vulnerable subjects as research participants needs special justification. Vulnerable subjects include those in prison, minors and persons with mental disability. Particularly in international research, it is important to ensure that the population in which the study is conducted will benefit from any potential outcome of the research. They should not be doing it to the benefit of another population. Justification is needed for any inducement, financial or otherwise, for participants to be enrolled in the study. Describe how interventions are justified, in terms of risks/benefits ratio. Psychological and social risks must also be considered, as well as confidentiality.

References
The protocol should end with relevant references on the subject. Generally, this should include no more than 20+ key references that demonstrate a thorough review of the literature and provide support for the methodology, design, etc. References and additional sources of information should be included following the APA format.

Timeline
In addition to the protocol, the student should also develop a timeline for study completion including, additional study development, necessary reviews, staff training, enrollment and follow up, data cleaning, analysis and publication.

Budget
A budget including costs of study assessments and personnel time should be developed using the NIH 398 budgeting forms.

SECTION IV: THESIS PROPOSAL FORM

Students are required to submit a Thesis Proposal Form by August 1st of their second year in the program. The Thesis Proposal form facilitates early communication between the student and the Thesis Advisor on the proposed project. The proposal requires students to briefly outline the topic and significance of the thesis, the data collection and analysis plan, and if IRB approval will be required to conduct the project. Both the student and the Thesis Advisor will sign off on the form. It should then be submitted to MSCI program leadership at MSCI@stjude.org.

Failure to submit the Thesis Proposal Form by the August 1st deadline may impact a student's grade in the Thesis Research Project course, which in turn can impact a student's Good Academic Standing in the MSCI program.

SECTION V: THESIS OPTIONS COMPARISON

Each of the thesis options will have a preferred format, contain similar information and be of approximately equal length of between 30-50 pages, not including references, appendices, and other supporting documents. Content should drive the length of each thesis project. Any significant deviations from the required thesis project content or length must be pre-approved by the student's Thesis Committee and the program Associate Deans in writing. Content of Completed Research and Prospective Clinical Research Study Options

<table>
<tr><th>Completed Research Option</th><th>Prospective Clinical Protocol Option</th></tr>
<tr><td>Introduction</td><td rowspan="2">Background and Rationale; Objectives</td></tr>
<tr><td>Literature Review</td></tr>
<tr><td>Statement of the Hypothesis to be Tested</td><td>Statement of the Hypothesis to be Tested</td></tr>
<tr><td rowspan="4">Methods</td><td>Study Design</td></tr>
<tr><td>Eligibility Criteria</td></tr>
<tr><td>Treatment Plan</td></tr>
<tr><td>Evaluations</td></tr>
<tr><td>Results</td><td>Outcomes; Analysis Plan</td></tr>
<tr><td>Discussion</td><td>Consent Forms</td></tr>
</table>

SECTION VI: THESIS COMMITTEE

The MSCI Thesis Committee plays a valuable role in the development, satisfactory progress, and evaluation of the Thesis. The Committee will advise and guide the student in the development of the Thesis.

Selection of Thesis Advisors

- Students enroll in thesis hours in the third semester of coursework, and during the fourth semester their time is predominantly devoted to researching, writing, and defending the thesis.
- A Thesis Advisor will be selected to oversee the preparation of the thesis.
- The Thesis Advisor will oversee the selection of the Thesis Committee and serve as the Chair of the Thesis Committee.
- The Thesis Advisor will assign student grades for the thesis hours courses based on student progress and the quality of the student research

Thesis Advisors

- The primary Thesis Advisor must be a member of the St. Jude Graduate School Faculty at the rank of Member or Associate Member.
- The Thesis Advisor oversees and directs graduate student research and guides the graduate student to successful acceptance of the thesis for the completion of the MSCI degree.

Thesis Committees

- All students enrolled in the MS In Clinical Investigations must submit the Thesis Committee Selection form by May 1 of their first year in the program.
- The Thesis Committee is comprised of at least 3 St. Jude Graduate School faculty members:
    - The primary Thesis Advisor who must hold the rank of Member or Associate Member
    - One representative from the student's academic field of interest at any faculty rank
    - One epidemiologist or biostatistician from the Department of Biostatistics or the Department of Epidemiology and Cancer Control at any faculty rank
    - Additional members may be added at any time to provide supplemental expertise via a written request from the Thesis Chair and with approval of the Associate Dean(s) and Dean. These members may be extramural from the St. Jude Graduate School.
- Students are required to meet at least four times with the Thesis Committee during their second year of the program (i.e., 3rd and 4th semesters).
- Upon completion of the thesis project, and with the Thesis Advisor's approval, students will undergo a scheduled, formal thesis defense. All members of the Thesis Committee are voting members. The Associate Dean(s) will attend thesis defenses as ex-officio, non-voting members. Members of the public may attend a thesis defense as observers only.
- After final approval of the Thesis and a full review of the student's academic record, and in consultation with the Dean and Associate Dean(s), the Thesis Advisor and Thesis Committee determines the student's successful completion of the requirements for the MS degree.
- In situations when the student's Thesis work as evaluated by the Thesis Committee does not meet the standards required to award the academic degree, the student may revise the submitted work. After discussion with the Thesis Advisor the student may submit for consideration the revised work to the Thesis Committee.

- Any requested changes to the Thesis Committee must be submitted for review and approval to the Dean and Associate Dean(s) in writing by the Committee Chair with a justification for the proposed modifications.

Roles and Responsibilities

The Committee Chair has special responsibilities in the Committee. The Chair manages and leads the outlined processes for ensuring satisfactory progress of the degree candidate, communicates with the student to set clear expectations around their deliverables, and should be the primary point of contact especially if unforeseen challenges arise.

- Chairs the Thesis Committee; Signs off on all required paperwork.
- Assists in developing a quality proposal, providing guidance on the structure, formatting, and content, based on program guidelines; Guides the student to identify a pragmatic approach and methodology and relevant plans for sharing findings.
- Steers the student towards achieving a high level of technical and ethical quality; Advises the student on navigating the IRB approval process, if relevant.
- Guides the student in selection of committee members in areas requiring subject matter expertise; Familiarizes the Committee members with the roles of the Chair and the other members; Manages conflict among committee members (e.g., personal conflict and intellectual disputes that create a roadblock for the student); Guides the student on how to proceed if a member of the committee is not responsive in a reasonable amount of time; may need to intervene directly if the problem is extreme. If all efforts fail, encourages the student to consider finding a replacement.
- Ensures that the student schedules and plans committee meetings ahead of time, in alignment with program milestones; Attends all Committee meetings.
- Assists the student in preparing for the Defense; Chairs the Defense and leads the evaluation process.

The Thesis Committee assists in preparing the project proposal, meets with the graduate student regularly during their second year, assesses student progress via the student's submitted chapters, meetings, and proposal presentation and submits a formal report and recommendations to the Dean together with a final copy of the graduate student presentation. In close coordination with the Chair, the Committee:

- Advises the student from the initial phase through the final defense (required commitment of a minimum of 12 months or until graduation).
- Contributes to the Thesis proposal and evaluation milestones by providing resources and guidance in areas of expertise, guiding the student in the selection of methods/procedures for data collection and analysis, reviewing and providing feedback on drafts of the thesis and deliverables at each milestone, and corresponding with the student and Chair for clarification/solution of methodological issues
- Attends and participates in the Thesis Defense, contributes to the evaluation, and signs off on the approval of the Thesis.

After full review of the student's thesis, and in consultation with the Dean and Associate Dean, the Chair and the Thesis Committee determine successful completion of the thesis requirement, which is a mandatory milestone for the MSCI degree.

Meetings – Frequency and Participation

- The frequency of meetings is outlined in Section IV: Thesis Milestones.
- The student and Chair are expected to attend all meetings.

The other *full* Committee meetings should ideally include all three (or four, if applicable) members of the Thesis Committee. Students should make every effort to convene the full Committee with all members. If all members are not available within a reasonable timeframe, at least two members of the Committee should attend.

Declaration of Thesis Committee

Students may consult advisors and mentors, the MSCI Program staff, and Committee Chairs prior to naming their Committee. However, the identification of the Chair and Committee members is the sole responsibility of the student.

To officially declare the members of the Thesis Committee, all students must submit a completed *Thesis Committee Agreement Form* with all required signatures.

SECTION VII: THESIS MILESTONES AND SUGGESTED TIMELINE

Year 1:

May 1
- Thesis Committee Agreement form submitted
- Conceptualize thesis topic

Year 2:

June
- First meeting with Thesis Committee (1 of 4 total required meetings)
- Assess any relevant IRB requirements

August 1
- Thesis Proposal Form completed and submitted

September
- Meet with Thesis Committee (2 of 4 required meetings)
- Submit drafts of 2 chapters/sections of thesis to Chair for feedback

November
- Submit drafts of 2 more chapters/sections of thesis to Chair for feedback

December
- Meet with Thesis Committee (3 of 4 required meetings)

January
- Submit drafts of 2 more chapters/sections of thesis to Chair for feedback

February
- Submit revisions of first drafts of sections/chapters previously submitted to Chair
- Complete any remaining chapters/sections of thesis

March/April
- Meet with Thesis Committee (4 of 4 required meetings)
- Continue all revisions

May
- Thesis defense scheduled before or on May 3
- If corrections/revisions requested during the defense, complete by May 24
- By May 24, submit final copy of thesis to the St. Jude Graduate School of Biomedical Sciences

SECTION VIII: THESIS DEFENSE

Format

The format of the Thesis Defense will be a 90-minute in-person, virtual or hybrid meeting, including 30 minutes for the student to present his/her Thesis, 30 minutes for attendees to ask questions, 15 minutes of deliberation by the Committee and Program team, and 15 minutes for feedback to the student. Prior to the Thesis Defense, the student should submit the Thesis (for iThenticate) and a slide deck (10-30 slides) via Canvas.

Students should submit the final Thesis to their Committees at least one week prior to the Defense.

Attendees:

- Required: Chair and all Committee members; the Chair will lead the discussions and assessment; one of the Program Associate Deans
- Optional Additional Attendees: Program Team, Graduate School Dean, fellow students, families, colleagues, etc.

Criteria for Evaluation

It is the responsibility of the Thesis Committee to determine whether the thesis has been completed satisfactorily. The thesis and defense will be evaluated based on select criteria developed by the MSCI Program and summarized in the rubric below.

The committee will reach one of the following results at the end of the defense:

- Approved (no revisions required),
- Approved with minor revisions, or
- Approved pending significant revisions.

Based on the recommendations of the Committee, the Chair will communicate the results to the student at the end of the defense and in writing to the student and Program Team within three business days. The committee will review the changes submitted and the Chair will inform the Program Team with the final decision. The rubric below is provided as a guideline for Thesis Committees to evaluate the thesis document.

	Deficient (1)	Acceptable (2)	Proficient (3)	Exemplary (4)	Overall Score
Background Knowledge and Problem Definition The student must display a deep understanding of the thesis topic. The student must also have broad knowledge of the general concepts and principles of health and health systems. The student must clearly frame the health problem in a succinct problem statement and provide the rationale for the focus.	__ No or poor application of health concepts __ Inadequate breadth and depth of understanding of the focus area __No real need or clearly described potential impact demonstrated	__ Limited application of health concepts __Sufficient breadth or depth (but not both) of the focus area __Demonstrates a moderate need with limited outreach and potential impact	__ Significant application of health concepts __Sufficient breadth and depth of understanding of the focus area __ Proposal demonstrates a significant and timely need for the project with limited outreach and potential impact	__ Comprehensive application of health concepts __Solid breadth and depth of knowledge of the focus area __Proposal demonstrates a significant and critical timely need for the project with potentially far reaching and sustainable impact	__ 1 __ 2 __ 3 __ 4

	Deficient (1)	Acceptable (2)	Proficient (3)	Exemplary (4)	Overall Score
Research, Synthesis and Results The student must describe and apply sound research methods/tools using key sources of insight to provide a rationale for the focus area and proposed project plan.	__ Information used from only a few (2-3) sources and not integrated __ Does not evaluate background literature __ Does not understand implications of existing research on the proposed project __ Does not provide rationale for the proposed plan	__ Information used from several (5-10) sources and not integrated __ Could synthesize background literature but no discussion __ Limited understanding of implications of existing research __ Has difficulty explaining rationale	__ Information from multiple (>10) sources used, but not integrated __ Could identify and discuss key findings from literature review __ Some attempts at discussing implications of most important research findings __Provides partial rationale based on research findings	__ Able to integrate information from multiple sources __ Able to describe, discuss, critically evaluate relevant background information __ Could draw clear conclusions from and discuss implications of most important research findings __Provides clear rationale based on research findings	__ 1 __ 2 __ 3 __ 4

	Deficient (1)	Acceptable (2)	Proficient (3)	Exemplary (4)	Overall Score
Approach, Strategy, and Evaluation The student must present an approach and implementation plan that is clearly described and logical with distinct goals. The student must also present appropriate expected and alternative outcomes, limitations, and ways to address potential challenges.	__ Proposal has ill-defined goals and/or does not include realistic or effective strategies to achieve intended goals. The goals don't relate well to the need identified. __ Does not identify limitations and assumptions in the project proposal __ Unaware of alternative approaches	__ Proposal includes goals relevant to the identified need, but the work proposed to achieve these goals does not align with the goals. __ Rationale for selected approach is not well- established __ Some awareness of alternative approaches	__ Proposal includes realistic goals relevant to the identified need, but the work proposed to achieve these goals is not innovative __ Rationale for selected approach included but need some modification __ Could identify strengths and weaknesses of approach __ Demonstrates understanding of alternative approaches	__ Proposal has clear goals, and presents an innovative strategy for achieving them; the proposal includes a well-thought-out timeline and evidence-based techniques. __ Able to identify and logically discuss strengths and weaknesses of the approach __ Appropriately compared and discussed alternative approaches	__ 1 __ 2 __ 3 __ 4
M & E: The student must develop Monitoring and Evaluation strategy for the project.	__No monitoring and evaluation strategy. The student does not list appropriate indicators, outputs and/ or outcomes of the project.	__Outlines some indicators and possible measures of gauging effectiveness but lacks a clear strategy.	__ Outlines a monitoring and evaluation strategy with indicators, outputs and outcomes requiring clarity.	__Outlines a robust monitoring and evaluation strategy with clear indicators, outputs and outcomes.	__ 1 __ 2 __ 3 __ 4

	Deficient (1)	Acceptable (2)	Proficient (3)	Exemplary (4)	Overall Score
Critical Thinking The student must critically evaluate background information, distinguish multiple sources of knowledge, including research-based knowledge and practical insights, in the process of framing the problem, logically discuss strengths and weaknesses of the proposed plan, interpret expected outcomes, clearly relate outcomes to criteria for success, draw clear conclusions and consider appropriate future directions.	__ Negligible awareness of important background information __ Difficulty relating results of the research to problem statement and approach __ Difficulty identifying limitations and assumptions in the project plan __ Difficulty designing alternative approaches and corrective strategy	__ Limited awareness of background information __ Able to evaluate literature but has difficulty explaining rationale of the proposed plan __ Awareness of some weaknesses in the project plan __ Awareness of some alternative approaches but no corrective strategy	__ Could discuss key background for the thesis __ Showed ability to draw clear conclusions from important research findings __ Could identify strengths and weaknesses of the project plan __ Showed ability to identify some alternative approaches and corrective strategy	__ Able to integrate information from multiple sources __ Able to describe, discuss, critically evaluate relevant background information __ Could draw clear conclusions from and discuss implications of most important research findings in context of the thesis topic __ Able to identify and logically discuss strengths and weaknesses of the project plan __ Appropriately considered alternative approaches and corrective strategy	__ 1 __ 2 __ 3 __ 4

	Deficient (1)	Acceptable (2)	Proficient (3)	Exemplary (4)	Overall Score
Communication The student must clearly describe and articulate the problem and project design in the written thesis and oral presentation. The student must be able to defend his/her rationale for specific approaches and respond to critiques in a professional and knowledgeable manner.	__ Written thesis did not follow standard format __ Grammatical errors and misspellings __ Arguments are incomplete or poorly organized __ Did not understand/ address the questions asked __ Poor oral communication skills	__ Sub-standard writing resulting in lack of clarity __ No grammatical errors or misspellings __ Some portions of the arguments are logical and organized __ Understood most of the questions but provided only partial answers __ Oral presentation was clear, but monotonous and student had to read the slides most of the time	__ Written thesis was largely well-written __ Arguments are logical and organized __ Understood questions and provided adequate answers __Could be readily understood __ Mostly clear but some discontinuities during the oral presentation	__ Written thesis was clearly written in the appropriate format __ Arguments are articulated and well-organized __ Understood the questions and provided clear, thorough answers __ Poised and polished in the oral presentation __ Engaged the committee and other audience in a collegial discussion	__ 1 __ 2 __ 3 __ 4

SECTION IX: ETHICAL CONSIDERATIONS

Expectations in a Professional Context

Professional behavior and maintaining professional communication and relationships with all stakeholders involved is expected of all students wherever they are located, as they represent not only the values of the MSCI Program but those of St. Jude Children's Research Hospital. Students are expected to maintain professional communication and relationships with the host organization, its staff, and all its constituents.

Use of Human Subjects

Research with human participants includes not only medical or biological research but also surveys, interviews, and records review. Students are responsible for educating themselves on how to protect the stakeholders, including the communities they serve, from risk of personal or professional harm. Students who conduct research with human subjects as part of their Projects should refer to the local guidelines on use of human subjects and/ or the equivalent of the institutional review board (IRB). Students should seek support from their Thesis Committee about regional and/ or sector-specific resources to prepare them.

In addition, all students are expected to have completed Section 5 of CITI training as a part of the Graduate School Orientation. In this training, students will have learned about the Declaration of Helsinki. Students are expected to review the Declaration of Helsinki prior to starting their theses:
https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for- medical-research-involving-human-subjects/

Documenting the Contributions of Others and Plagiarism (iThenticate)

- Academic integrity is the pursuit of scholarly activity in an open, honest, and responsible manner. All students shall act with personal integrity; respect other students' dignity, rights, and property; and help create and maintain an environment in which all can succeed.
- Dishonesty of any kind will not be tolerated. Dishonesty includes, but is not limited to, cheating, plagiarism, and fabricating or falsifying information or citations; facilitating acts of academic dishonesty by others; having unauthorized possession of examinations; submitting work of another person as the student's own or work previously used without informing the instructor; and tampering with the academic work of other students.
- The Graduate School uses iThenticate to screen documents (including papers, theses, dissertations, etc.) for copied text to ensure originality and the proper use of citations. iThenticate is an anti-plagiarism software that runs the uploaded document against the world's top published works and 70+ billion current and archived webpages.

Guidelines on Public Availability and Confidentiality

Completed theses will be stored in the Graduate School's repository. Embargoes may be placed on theses to prevent their public availability as needed.

SECTION X: APPENDICES

Appendix A: References

References

List citations for literature, websites, books, etc., referenced. Use reference management software, such as EndNote, provided free to students. Use APA citation style.

Appendix B: Tables

Tables

Table 1

Sample Table Title

(Table goes here)

The caption goes below the table and would involve anything that you want to include as a "*Note*" or if you have *, [a], [b], abbreviations, etc. that you need to clarify. The utility is to provide more information about the table if needed. Here are a few examples: https://apastyle.apa.org/style-grammar-guidelines/tables-figures/sample-tables

(If no tables, omit this page. Table font should be the same as the rest of the Thesis: Times New Roman size 12.)

Appendix C: Figures

Figures

Figure 1

Sample Figure Title

(Figure goes here)

The caption goes below the figure and would involve anything that you want to include as a "*Note*" or if you have *, [a], [b], abbreviations, etc. that you need to clarify. The utility is to provide more information about the figure if needed. Here are a few examples: https://apastyle.apa.org/style-grammar-guidelines/tables-figures/sample-figures

(If no figures, omit this page. Figure font should be the same as the rest of the Thesis: Times New Roman size 12.)

Appendix D: Appendices

Appendices

Appendix A

Sample Appendix Title

(If no appendices, omit this page. Appendix font should be the same as the rest of the Thesis: Times New Roman size 12.)

Appendix E: Thesis Front Matter

ENTER TITLE IN ALL CAPS
Student Name

A Thesis

Submitted to the St. Jude Children's Research Hospital
Graduate School of Biomedical Sciences
in partial fulfillment of the requirements for the degree of
Master of Science

Master of Science in Clinical Investigations

Memphis, Tennessee

Month and Year

Committee:

First and Last Name, Advisor

First and Last Name

First and Last Name

First and Last Name

First and Last Name

Dedication Text

[Enter text here]

Acknowledgements

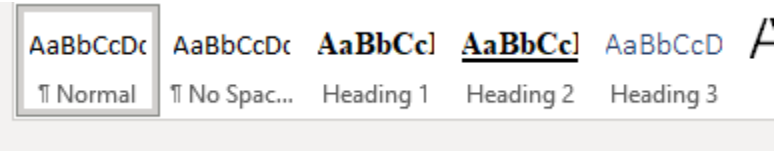
[Enter text here]

Table of Contents

Each thesis should have a detailed Table of Contents that includes all sections/chapters, subheadings within chapters as appropriate, and corresponding page numbers.

Microsoft Word has an automatic TOC creation feature that you can use, so long as you program you headings and sub-headings correctly.

At the top of the Home bar, you will see many options for text headings:



You can right click on each type of text and program the font, bold/italics, etc.

The main text of your thesis should be "Normal."

Anything you want to be a main heading in your TOC should be Heading 1. To make the text Heading 1, type, highlight it, and then click on "Heading 1".

If you would like sub-headings in your TOC, then use Heading 2. If you want further section headings, you can choose heading 3, etc. Anything that you do not want to appear in your TOC should be Normal.

When you are ready to generate a TOC, place your cursor on the page where you want it to be. Under the References tab, select Table of Contents. You can use any of the pre-programmed formats or create your own. Your TOC will be automatically created.

If you make edits that impact the TOC, you will have to update it. To do so, at the top of the TOC, click on "Update Table" and "Update Entire Table." This will update page numbers as well as all headings.

The TOC that is created by Word is also navigable. You can click on the page number and the document will take you directly to that page. This is helpful for those reading your thesis in electronic format.

List of Tables

List of Figures

List of Appendices

Appendix F: Thesis Reference Guide and Formatting

When preparing the thesis for submission, students must follow these formatting requirements. Any deviation from these requirements may lead to rejection of the thesis and delay in conferral of the degree. Most of these formatting guidelines have been incorporated within the templates.

Length

Most theses are approximately 30 - 50 pages in length, not including front matter, references, and appendices. All theses should be divided into appropriate sections; long theses may need chapters, main divisions, and subdivisions.

- Front Matter
  - Signature Page
  - Copyright
  - Abstract
  - Dedication
  - Acknowledgements
- Table of Contents
- All Thesis Chapters/Sections
- References
- Tables
- Figures
- Appendices

Page Size

- 8.5 x 11

Font Type and Size

- Times New Roman (Including page numbers and footnote numbers) is preferred.
- 12-point font size, but a smaller type size may be used if student's committee members agree to this.
- Specialized fonts appropriate for typesetting needs (such as formulas and equations) may be used if approved by student's committee

Margins

- 1.0" top, right, left and bottom
- A 1.50" left margin may be used only if a student wishes to produce bound copies for their advisor, department, etc.

Justification and Hyphenation

- Align all text with the left-hand margin, except centered headings, paragraph indentations (at least 5 spaces required, although most styles require 10 spaces or .5" indentations for paragraphs), or block quotations (indent 5 spaces only, not 10).
- Full justification of margins is NOT acceptable; the right-hand margin must be jagged.

- Hyphenation at the right-hand margin is allowed as long as it does not cause difficulty in reading.

Spacing

- Double space all text unless stated differently in a particular style guide or refereed journal. This requirement includes only one double spaced line between all paragraphs, not triple.
- Double space between all paragraphs within centered/and or subheadings.
- Indent first word of each paragraph.
- Single spacing may be used for quotations, footnotes, tables, and references. Individual references should have at least one space between them.
- Single space footnote entries, but double space between each separate entry.
- Double space bibliography/references/works cited entries.

Tables and Figures

- Tables and figures should be on a separate page.
- Headings should be placed at the top of tables and figures.
- Captions should be placed at the bottom of tables and figures centered vertically and horizontally within the margins.
- Double space captions.

Page Numbers

- All page numbers should stand alone without any form of punctuation and should be in the upper right header. The last line of text must be 1" from the bottom.
- There must be NO page number displayed on the document title page.
- Preliminary pages, such as the Copyright, Dedication, Acknowledgement, Abstract, Table of Contents, List of Tables, List of Figures, or List of Abbreviations, etc. must be numbered in lowercase (small) Roman numerals beginning with "ii" and MUST be in the upper right header.
- Pages in the body of text must be numbered using Arabic numerals beginning with "1" and must also be in the upper right header of each page.

Subheadings

- Placement of chapters and/or section heads should be consistent throughout the entire document.
- Preliminary page titles (i.e., Abstract, Table of Contents, etc.) should each be treated as chapter titles in terms of formatting.
- Do NOT begin any subheading or other divisions on separate pages.
- If a subheading falls at the end of a page without any accompanying text, move it to the top of the next page.
- Do NOT include any extra lines between section heads, unless otherwise specified by a refereed journal.

- Do NOT use a numbering system for title and subheadings (e.g., 1.1, 1.1.1) unless required by style manual, refereed journal or approved by student's committee. If they are numbered, please send justification with review copy to the Registrar.

Running Headers, Footnotes, and Endnotes

- Running headers and endnotes are NOT allowed.
- If footnotes are used, they must conform to margin requirements. They must also begin on the page they are cited.
- Footnotes must be in size 10 font (whereas all other text must be size 12) unless specified required differently by student's committee.
- Single space each footnote entry and double space between each separate entry.
- Footnotes are NOT to be numbered consecutively throughout the text. At the beginning of each new chapter, begin each footnote number with the Arabic number "1."

Appendix G: Thesis Approval Forms

Thesis Committee Consensus Letter [Please use letterhead]

[Date]

RE: Thesis Committee Consensus: [Student Name (first and last)]

Dear Drs. Pat Flynn and Victor Santana,

It is a great pleasure to update you on the consensus of [Student Name]'s Thesis Committee, regarding development and defense of their thesis entitled: "[Thesis Title]."

[Insert a few sentences on the student's progress throughout the year. Include comments and observations on student's preparation, organization, creativity, resilience, etc.]

The Thesis Committee [select from Approves, Approves with Minor Revisions, or Does Not Approve] [Student Name]'s thesis following their defense. [Include any follow-up instructions sent to student, and date by which they must be completed].

Sincerely,

[Chair Signature]

[Chair name (first and last) and degree]

CC: [Student Name]

[Committee Member #2 name]

[Committee Member #3 Name]

[Committee Member #4 Name, if applicable]

[Assistant Dean of MS in CI Program]

Thesis Approval Signature Page

This thesis by Student is accepted in its present form

by his/her thesis committee as satisfying the

thesis requirement for the degree of Master of Science

Date,	Name, Advisor

Recommended to the President and Dean of the Graduate School

Date,	Committee Member, Reader
Date,	Committee Member, Reader
Date,	Committee Member, Reader
Date,	Committee Member, Reader

Approved by the President and Dean of the Graduate School

Date,	Dr. Steven Varga, President and Dean