Cleveland Clinic Lerner College of Medicine
of Case Western Reserve University

The Clinical Research Requirement
of the
Clinical Research Scholars Program
(CRSP)

Clinical Research Scholars Program,
Biomedical Investigation Program,
Lerner College of Medicine
Case Western Reserve University School of Medicine

CRSP Oversight Committee Members:

CRSP Director:	James Spilsbury, PhD	jcs5@case.edu
CRSP Director:	Christine Moravec, PhD	moravec@ccf.org
CRSP Executive:	A. Michael Lincoff, MD	lincofa@ccf.org
	Candece Gladson, MD	gladsoc@ccf.org
	Linda Graham, MD	grahaml@ccf.org
	Trine Jorgensen, PhD	jorgent@ccf.org
	Amy S. Nowacki, PhD	nowacka@ccf.org

For questions, please contact any of the following people:

- Christine Moravec moravec@ccf.org Phone: 216-445-9949
- Tanya Moore mooret2@ccf.org Phone: 216-403-1015
- Shannon Bettinger bettins2@ccf.org Phone: 216-598-8123

All appendices to the CRSP Oversight Committee should be directed to Tanya Moore and Shannon Bettinger via email.

TABLE OF CONTENTS

1. INTRODUCTION

Receipt of a master's degree in the Clinical Research Scholars Program (CRSP) requires completion of a research project in Clinical Research. The requirements for this project are outlined below. This program is a Plan B Master's degree supervised by the CRSP Oversight committee located in the Cleveland Clinic Lerner College of Medicine (CCLCM). It is open to medical students in the CCLCM or Case School of Medicine.

This document is a general summary of academic program information and should be used in consultation with an academic advisor. It is the student's responsibility to become acquainted with and adhere with all rules, regulations, and administrative procedures governing CCLCM and CRSP.

2. STUDENT RESPONSIBILITY

It is solely the student's responsibility to become acquainted with and adhere to Departmental/Center and University rules, regulations, and administrative procedures governing graduate study, including the University's Standards of Conduct detailed in the CWRU General Bulletin, Graduate Student Handbook, School of Graduate Studies Statement of Ethics, University Guidelines on Authorship and Policy on Copyright, and the University Policy on Academic Integrity.

3. TRACKS

It is strongly suggested that the CCLCM thesis research project be designed to fulfill the clinical research requirement of CRSP; that is, that the thesis project consists of or includes a component of clinical research (see definition Section 6). It is recognized, however, that there may be circumstances in which a student's thesis project does not meet criteria for clinical research, but the student is willing to conduct a separate independent clinical research project to satisfy the requirements for a CRSP degree. Although such an independent clinical research project does not need to be as extensive as the student's 1-year thesis research experience, it is expected that the clinical research project will be of magnitude and scope suitable for peer-reviewed publication.

Thus, students using their CCLCM thesis research project to fulfill the CRSP requirement are considered in the Thesis Project Track (see section 4. '**THESIS PROJECT TRACK'**). Students completing an independent clinical research project to fulfill the requirement are considered in the Independent Project Track (see section 5. '**INDEPENDENT PROJECT TRACK**').

4. THESIS PROJECT TRACK

Committee:
If a student is in the Thesis Project Track, there need not be a member of the CRSP Oversight Committee on the student's thesis committee, although a member of the CRSP Oversight Committee should be present at the defense.

Design of the Thesis Research Project:
It is expected that each medical student will become actively engaged in a clinical research project. This entails participation in all aspects of conducting clinical research, from inception to dissemination of results. It is possible for a student to independently conduct a new project, join an existing ongoing project, or be part of a larger effort.

Approval Process:

The clinical research project is an essential part of medical training as well as the master's degree. It is critical that it be developed in a timely and thorough fashion. A mentor and a general idea of the research project should be identified as early as possible. Once the project has been designed, the research project must be discussed in person with the CRSP Executive, who gives suggestions and final approval. **Schedule a meeting with the CRSP Executive as early as a reasonably developed plan has been generated (six months prior to the start of your research year is recommended, but minimally three months prior).**

For this meeting, bring the completed CRSP Research Project Description Form (Appendix 1A) which summarizes the study and the student's role in the study. The study description portion of this document is to be in summary form and should generally not exceed one-two pages. It must contain the following preliminary information:

a. Title
b. Brief background information
c. Need for the types of work being proposed
d. Hypotheses
e. Study design
f. Analysis plan
g. Potential problems
h. Approvals required and when they will be obtained
i. Feasible timeline

For students in the Thesis Project Track, the one-page project description that must be submitted to the Research Education Committee (REC) for CCLCM approval will normally suffice, assuming it contains the information listed above.

Feedback received during this meeting with the CRSP Executive must be addressed and the amended proposal submitted to the CRSP Executive for final approval prior to beginning the project. Approval may be either in the form of the CRSP Executive's signature on the CRSP Research Project Description Form or an email from the CRSP Executive indicating approval. No project will begin before the CRSP Executive gives approval. It is emphasized that development of a suitable project takes time. Every effort should be made to ensure that the approval is obtained well in advance of the proposed start date.

The student must identify within the appropriate Cleveland Clinic institute or the sponsoring organization the person or committee responsible for approval of research projects and receive approval of the project ensuring the feasibility of completion and support of the institute.

Carrying Out the Project:

All students in the Thesis Project Track must complete and submit the CRSP Research Project Update Form (Appendix 2A). Its purpose is to inform the CRSP Oversight Committee of progress towards, and any changes made to, the clinical research project. It should contain sufficient details to allow the committee to assess progress towards completion of the project.

The CRSP Research Project Update Form must be completed and submitted to the CRSP Oversight Committee within two weeks after the regular six-month meeting with the thesis committee. This document, which may be brief, is to provide an update on the progress of, and any changes made to, the Clinical Research component of the thesis project.

Completion of the Project:

At the completion of the clinical research project, all Thesis Project Track students must complete the following steps:

(A) Orally present study results

The normal thesis defense will satisfy this condition. The student is responsible to invite a CRSP Thesis Oversight Committee member to attend the defense. The CRSP representative does NOT need to be on the research committee, but instead just needs to attend the presentation of the research project. The student must notify the program manager of the thesis defense date and inform them of who will be in attendance from the CRSP Committee.

(B) Submit a CRSP Research Project Final Approval Form (Appendix 3A)

Students must produce a final written document describing the clinical research project. The written thesis document will satisfy this condition. This final written document must be submitted to the CCLCM thesis research committee. Each student must complete and submit a CRSP Research Project Final Approval Form to the CRSP Oversight Committee. This form serves to verify that the student has completed the written document component of the clinical research project to the satisfaction of their committee.

(C) Submit a CRSP Clinical Research Reflection (Appendix 4)

This is a one-page essay describing the student's research experience and should include the student's reflection upon the knowledge and experience gained during the formulation and completion of the clinical research project. Once completed, this form must be submitted to the CRSP Oversight Committee.

Timeline for Required Forms:

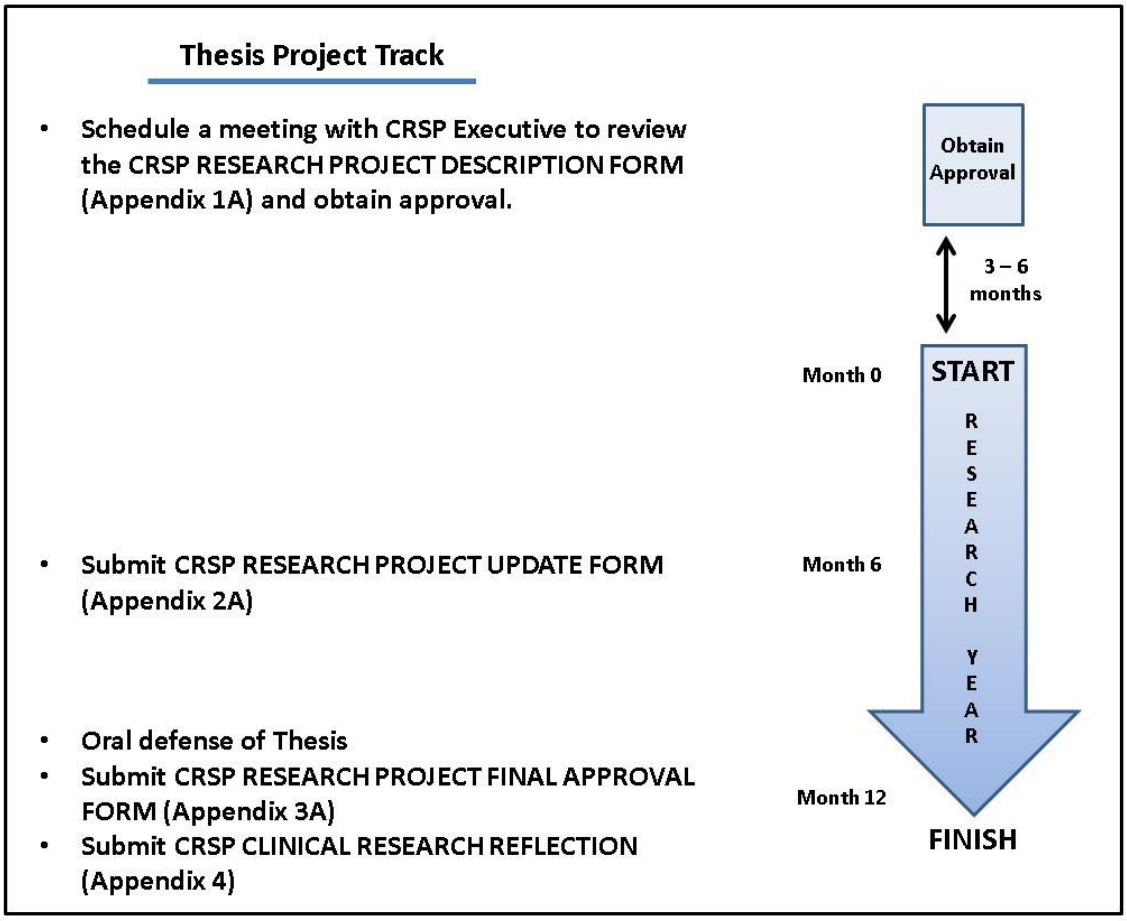

Figure 1

5. INDEPENDENT PROJECT TRACK

Committee:

If a student is in the Independent Project Track, this independent project will be overseen by a Clinical Research Committee; a committee of at least three faculty members which will be formed by the student. One member of this committee will be the Advisor. This is the study PI, laboratory head, or project leader. Another must be a member of the CRSP Oversight Committee. The third can be a knowledgeable person from the local research community. One of the latter two members must be designated as Chair of the Committee. The committee members must be approved by the CRSP Oversight Committee and indicate their willingness to serve at least 4 weeks prior to the beginning of the project (email confirmations are acceptable).

Design of the Independent Project:

It is expected that each medical student will become actively engaged in a clinical research project. This entails participation in all aspects of conducting clinical research, from inception to dissemination of results. It is possible for a student to independently conduct a new project, join an existing ongoing project, or be part of a larger effort.

Approval Process:

The clinical research project is an essential part of medical training as well as the master's degree. It is critical that it be developed in a timely and thorough fashion. A mentor and a general idea of the research project should be identified as early as possible. Once the project has been designed, the research project must be discussed in person with the CRSP Executive, who gives suggestions and final approval. **Schedule a meeting with the CRSP Executive as early as possible, but at least one month prior to the proposed start of your research study.**

For this meeting, bring the completed CRSP Research Project Description Form (Appendix 1B) which summarizes the study and the student's role in the study. The study description portion of this document is to be in summary form and generally should not exceed one-two pages. It must contain the following information:

a. Title
b. Brief background information
c. Need for the types of work being proposed
d. Hypotheses
e. Study design
f. Analysis plan
g. Potential problems
h. Approvals required and when they will be obtained
i. Feasible timeline

For students in the Independent Project Track, if the study is a continuation of a project upon which the student has been working, the student should highlight in the CRSP Research Project Description Form the new objectives that they will be investigating. If the study is part of a larger project that is ongoing, it will be necessary for the student to indicate the role they will play in the project. Clinical research performed during the second summer clinical research block cannot count towards the Clinical Research Requirements. However, continuation of this project with a new set of objectives may be appropriate. Work completed prior to approval by the CRSP Executive will not necessarily be considered toward fulfillment of this project.

Feedback received during this meeting with the CRSP Executive must be addressed and the amended proposal submitted to the CRSP Executive for final approval prior to beginning the project. Approval may be either in the form of the CRSP Executive's signature on the CRSP Research Project Description Form or an email from the CRSP Executive indicating his approval. No project will begin before the CRSP Executive gives approval. Development of a suitable project takes time. Every effort should be made to ensure that the approval is obtained well in advance of the proposed start date.
The student must identify within the appropriate Cleveland Clinic Institute or the sponsoring organization the person or committee responsible for approval of research projects and receive approval of the project ensuring the feasibility of completion and support of the Institute.

Carrying Out the Project:
All students in the Independent Project Track must complete and submit the CRSP Research Project Update Form (Appendix 2B). Its purpose is to inform the CRSP Oversight Committee of progress towards, and any changes made to, the clinical research project. It should contain sufficient details to allow the committee to assess progress towards completion of the project.

The CRSP Research Project Update Form must be submitted to the CRSP Oversight Committee and the student's Clinical Research Committee at the approximate mid-point of the proposed project timeline. If major changes are required in the project, the student is encouraged to call a meeting of the Clinical Research Committee.

Completion of the Project:
At the completion of the clinical research project, all Independent Project Track students must complete the following steps:

(A) Orally present study results
For students in the Independent Project Track, a presentation given to the CRSP Oversight Committee or to another scholarly group to which the CRSP Oversight Committee is invited will satisfy this condition. The presentation must be on the Cleveland Clinic campus. You are responsible to contact the CRSP Oversight Committee to schedule your presentation.

(B) Submit a CRSP Research Project Final Approval Form (Appendix 3B)
All students in the Independent Project Track must produce a final written document describing the clinical research project. A draft manuscript of publication quality will satisfy this condition. This draft manuscript should include an abstract, background information, methods, results, discussion and references. This final written document must be submitted to the Clinical Research Committee. Each student must complete and submit a CRSP Research Project Final Approval Form to the CRSP Oversight Committee. This form serves to verify that the student has completed the written document component of the clinical research project to the satisfaction of their committee.

(C) Submit a CRSP Clinical Research Reflection (Appendix 4)
This is a one-page essay describing the student's research experience and should include the student's reflection upon the knowledge and experience gained during the formulation and completion of the clinical research project. Once completed, this form must be submitted to the CRSP Oversight Committee.

Timeline of Required Forms:

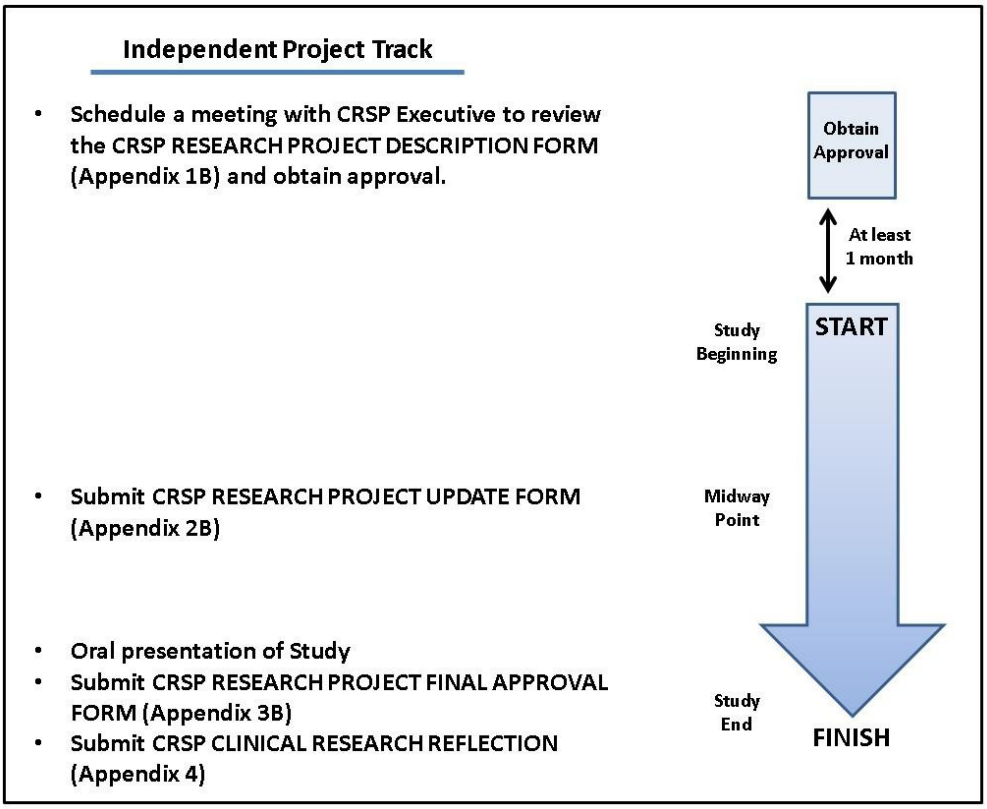

Figure 2

6. Definitions

Thesis research project:

The project done by each CCLCM student in completion of the research requirement for the MD. This project is approved and overseen by the CCLCM Research and Education Committee (REC).

Independent project:

Any project able to fulfill the Clinical Research requirement for the CRSP master's degree, which does not fulfill the CCLCM research requirement.

Second summer research:

Any work performed during the months of July thru September during the second summer.

Clinical Research **(as defined by NIH):** Research with human subjects that is:

1. Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens, and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. It includes:
    i. mechanisms of human disease
    ii. therapeutic interventions
    iii. clinical trials
    iv. development of new technologies

2. Epidemiological and behavioral studies.
3. Outcomes research and health services research.

Studies falling under 45 CFR part 46.101(b) (4) (Exemption 4) are not considered clinical research by this definition.

Clinical Research Committee:

The three-member committee is formed by students completing an independent project. This committee has responsibility to oversee and approve the project for the purposes of the CRSP master's degree.

Additional Information

IRB Approval of all Research and Protection of Data

All research involving human subjects, even if involving only secondary data analysis, must have IRB approval or a documented IRB determination of exemption. The program advisor, and/or the primary and co-mentors must be involved in this process. If the work is part of a larger project that has already received clearance, the student should be added as key personnel to the IRB protocol. All data must be securely maintained and privacy of participants protected. Students are required to adhere to the University's, School of Medicine's, and relevant IRB's data protection policies. Human subject data or study materials provided to, obtained from, or created by a student may not be transmitted or shared with any other individuals (including another student) without explicit written permission from the study's principal investigator and/or the responsible investigator listed on the approved IRB protocol.

Academic Integrity

Each student will be held responsible to adhere to the University's, School of Medicine's, and the programs' of standards of academic integrity. Any form of academic dishonesty (e.g. forgery, cheating, plagiarism, misrepresentation and obstruction, alteration of university documents, etc.) is a violation of academic integrity standards. Plagiarism includes, but not limited to, the duplication of another's words, work, or ideas from printed or electronic sources, without proper attribution, and pass as one's own. Note: It is considered plagiarism to submit, without the instructor's consent, a previously submitted assignment from one class to another.

If a student is deemed to have violated the standards of academic integrity, the University's Academic Integrity Board may take one of the following actions to sanction the student's violation:

1. Issuing failure in the work in question,
2. Issuing failure in the course,
3. University disciplinary warning,
4. University disciplinary probation,
5. University disciplinary suspension, or
6. Expulsion.

The University also has guidelines on authorship standards. Further details can be found in the University's policy on Academic Integrity:
http://www.case.edu/gradstudies/current/policies.html

APPENDIX 1A
CRSP RESEARCH THESIS PROJECT DESCRIPTION FORM

This form is to be completed by a student in the Thesis Project Track and brought to the meeting with the CRSP Executive. After obtaining approval from the CRSP Executive, the student should meet with their Thesis Advisor to review this form and obtain approval from their Thesis Advisor. Upon approval by both the CRSP Executive and the Thesis Advisor, this form must be submitted to the CRSP Oversight Committee.

Student Name: _____

Title of the project: _____

Approximate start date of project: _____

Anticipated completion date of project: _____

Thesis Research Committee Members:

Thesis Advisor_____

Committee Chair _____

Member_____

Member_____

a. Attach to this form a brief description of the project. Please keep within two pages. Include: title; brief background information; need for the work; hypotheses; study design; analytical plan; potential problems; approvals required and when they will be obtained; and a proposed timeline. You may use the one-page project description that must be submitted to the Research Education Committee (REC) assuming it contains this information.
b. The student must identify within the appropriate Cleveland Clinic institute or the sponsoring organization the person or committee responsible for approval of research projects and receive approval of the project ensuring the feasibility of completion and support of the institute.

□ Approval Received Student Initials _____
□ Not applicable to this study

c. It is expected that each student will become actively engaged in a clinical research project. Place a check next to the activities that describe your role in the proposed clinical research study. Select as many of the active components as appropriate. It will be up to the discretion of the CRSP Executive whether there is substantial work proposed.

ACTIVE **PASSIVE**

(1) Develop the research question

- ☐ Literature review
- ☐ Write introduction/background section of a manuscript

(2) Study Design

- ☐ Define study group(s)
- ☐ Define the outcome(s)
- ☐ Select a study design
- ☐ Identify inclusion/exclusion criteria
- ☐ Develop a statistical analyses plan
- ☐ Write a methods section of a manuscript

- ☐ Critique study group(s)
- ☐ Critique the outcome(s)
- ☐ Critique the study design
- ☐ Critique inclusion/exclusion criteria
- ☐ Consult a biostatistician

(3) Permission

- ☐ Write or revise IRB submission
- ☐ Read & critique IRB submission(s)

(4) Data Collection

- ☐ Design data collections form(s)/survey (REDCap if possible)
- Prospective Study:
  - ☐ Consent and enroll patients
  - ☐ Collect and/or record data
- Retrospective Study:
  - ☐ Obtain dataset (EResearch, Registry, GetData, etc.)
  - ☐ Perform chart review

- ☐ Critique data collection process
  - o Appropriate data collection instruments?
  - o Forms understandable?
  - o Missing data issues?
  - o Issues with recruitment?

(5) Data Analyses

- ☐ Perform statistical analyses
- ☐ Interpret results
- ☐ Write results section of a manuscript
- ☐ Write discussion section of manuscript (place results in context of previous studies)

- ☐ Gain basic understanding of analytical techniques utilized by biostatistician

Signatures: Student_____ Date _____

CRSP Executive_____ Date _____

Thesis Advisor_____ Date _____

APPENDIX 1B

CRSP INDEPENDENT RESEARCH PROJECT DESCRIPTION FORM

This form is to be completed by a student in the Independent Project Track and brought to the meeting with the CRSP Executive. After obtaining approval from the CRSP Executive, the student should meet with their Clinical Research Committee Advisor to review this form and obtain approval from the Advisor. Upon approval by both the CRSP Executive and the Advisor, this form must be submitted to the CRSP Oversight Committee.

Student Name:_____

Title of the project: _____

Approximate start date of project: _____

Anticipated completion date of project: _____

Clinical Research Committee Members:

Advisor _____

CRSP Committee Member _____

Other _____

a. Attach to this form a brief description of the project. Please keep within two pages. Include: title; brief background information; need for the work; hypotheses; study design; analytical plan; potential problems; approvals required and when they will be obtained; and a proposed timeline.

b. The student must identify within the appropriate Cleveland Clinic institute or the sponsoring organization the person or committee responsible for approval of research projects and receive approval of the project ensuring the feasibility of completion and support of the institute.

- ☐ Approval Received Student Initials _____
- ☐ Not applicable to this study

c. It is expected that each student will become actively engaged in a clinical research project. Place a check next to the activities that describe your role in the proposed clinical research study. Select as many of the active components as appropriate. It will be up to the discretion of the CRSP Executive whether there is substantial work proposed.

ACTIVE	PASSIVE
(1) Develop the research question	
◻ Literature review	
◻ Write introduction/background section of a manuscript	
(2) Study Design	
☐ Define study group(s)	◻ Critique study group(s)
☐ Define the outcome(s)	◻ Critique the outcome(s)
☐ Select a study design	◻ Critique the study design
☐ Identify inclusion/exclusion criteria	◻ Critique inclusion/exclusion criteria
☐ Develop a statistical analyses plan	◻ Consult a biostatistician
☐ Write a methods section of a manuscript	
(3) Permission	
◻ Write or revise IRB submission	◻ Read & critique IRB submission(s)
(4) Data Collection	
☐ Design data collections form(s)/survey (REDCap if possible)	☐ Critique data collection process o Appropriate data collection instruments? o Forms understandable? o Missing data issues? o Issues with recruitment?
• Prospective Study: ◻ Consent and enroll patients ◻ Collect and/or record data	
• Retrospective Study: ◻ Obtain dataset (EResearch, Registry, GetData, etc.) ◻ Perform chart review	
(5) Data Analyses	
☐ Perform statistical analyses	◻ Gain basic understanding of analytical techniques utilized by biostatistician
☐ Interpret results	
☐ Write results section of a manuscript	
☐ Write discussion section of manuscript (place results in context of previous studies)	

Signatures:

Student _____

CRSP Executive_____ Date _____

Advisor_____ Date _____

APPENDIX 2A

CRSP RESEARCH THESIS PROJECT UPDATE FORM

This form is to be submitted by a student in the Thesis Project Track to the CRSP Oversight Committee. It is to be submitted within two weeks after the normal six month meeting of the CCLCM Thesis Research Committee.

Date: _____

Student Name: _____

Project Title: _____

Date the project was initiated: _____

Anticipated completion date of project: _____

Attach to this form a brief update on the progress towards completion of the Clinical Research component of the thesis project; work remaining; problems encountered; how these problems will be addressed; and any changes in the expected outcome, methods, or overall goals of the work. Please keep within two pages.

Signatures:

Student _____

Thesis Advisor _____

APPENDIX 2B

CRSP INDEPENDENT RESEARCH PROJECT UPDATE FORM

This form is to be submitted by a student in the Independent Project Track to the CRSP Oversight Committee and the student's Clinical Research Committee. It is to be submitted at the approximate mid-point of the proposed project time line.

Date: _____

Student Name: _____

Project Title: _____

Date the project was initiated: _____

Anticipated completion date of project: _____

Attach to this form a brief update on the progress towards completion of the independent clinical research project; work remaining; problems encountered; how these problems will be addressed; and any changes in the expected outcome, methods, or overall goals of the work. Please keep within two pages.

Signatures:

Student _____

Advisor _____

APPENDIX 3A

CRSP RESEARCH THESIS PROJECT FINAL APPROVAL FORM

This form is to be submitted by a student in the Thesis Project Track to the CRSP Oversight Committee at the conclusion of their clinical research project.

Date: _____

Student Name: _____

Project Title: _____

Date the project was initiated: _____

Date the project was completed: _____

Attach to this form the final CCLCM thesis document which should contain as part of the document a description of the clinical research component of your work. Please include an abstract, background, hypothesis, methods, results, discussion and references.

Signatures on this form verify that the named student has completed the clinical research component of their thesis and provided a written document (the thesis) describing this component to the satisfaction of the CCLCM Thesis Research Committee.

Signatures:

Student _____

Thesis Advisor_____

APPENDIX 3B

CRSP INDEPENDENT RESEARCH PROJECT FINAL APPROVAL FORM

This form is to be submitted by a student in the Independent Project Track to the CRSP Oversight Committee at the conclusion of their clinical research project.

Date: _____

Student Name: _____

Project Title: _____

Date the project was initiated: _____

Date the project was completed: _____

Attach to this form a written document containing a description of your clinical research study. It should be presented in the form of a paper for publication. This manuscript should include an abstract, background information, methods, results, discussion and references.

Signatures on this form verify that the named student has completed the clinical research project and provided a written document (manuscript) describing this study to the satisfaction of the Clinical Research Committee.

Signatures:

Student _____

Clinical Research Committee Members:

Advisor_____

CRSP Committee Member _____

Other _____

APPENDIX 4

CRSP CLINICAL RESEARCH REFLECTION

This form is to be completed by all students at the conclusion of their clinical research project. Please submit this form to the CRSP Oversight Committee.

Date: _____

Student Name: _____

Project Title: _____

Date the project was initiated: _____

Date the project was completed: _____

Attach to this form a reflection upon the knowledge and experience gained during the formulation and completion of the Clinical Research Project. Please keep within one page.

Signatures:

Student _____