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Goals of Thesis Experience

The thesis project represents the culmination of research training at CCLCM. The purpose of this curricular component is to provide an in-depth, substantive research experience that builds on the research skills learned during medical school. Specific goals for this requirement are:

- 1. Demonstrate the ability to formulate and articulate a hypothesis driven research proposal
- 2. Demonstrate skills necessary to:
 - a. Perform studies using appropriate methodology
 - b. Critically analyze results, including an understanding of appropriate statistics
 - c. Interpret results, draw conclusions, and understand limitations
- 3. Strengthen ability to work as a member of a research team by integrating into a research working group and presenting work in progress to research colleagues
- 4. Strengthen skills in scientific presentation including the use of graphics and presentation software
- 5. Strengthen scientific writing skills that effectively communicate research findings

Student Responsibilities

Choose a thesis advisor. Work with the thesis advisor to create a project that can reasonably be completed within one year and has a component that can be defined as the "student's own". The project should have sufficient depth to potentially lead to a first author publication.

If the proposed thesis advisor has not mentored a CCLCM year-long research student, submit the potential advisors NIH Biosketch and a project description (**not to exceed two pages**) to The Research Education Committee for approval of the mentor. The study description should include the following: a title, relevant background information, need for the type of work being proposed, an overarching hypothesis, 2-3 specific aims, study design (including pertinent features – controls and power analysis if applicable), analysis plan, potential problems, feasibility of the study (time line) and appropriate approvals (i.e. IRB, IACUC).

With the input of the thesis advisor, select thesis committee members according to the guidelines on page 12. Be sure that the thesis committee includes at least one member who is not directly involved in the project. A copy of the project description (as described in the previous paragraph) should be provided to each potential committee member when they are contacted regarding participation in the project.

Complete the Thesis Project Information form and Funding during Research form via the electronic forms link under resources on the CCLCM Portal and attach all supporting documents. Once the project has been approved by the REC, this form will be submitted to obtain signatures from the thesis advisor, committee chair and physician advisor. After the form has been signed and approved the student will receive official notification from the Research Education Office that the project has been approved.

Submit all necessary IRB/IACUC protocols to proceed with the project. Revise as necessary to ensure approval of the project **prior** to thesis start. Student must be named as a study participant and provide approval by submitting the IRB protocol number to the Research Education Office prior to project start. **All Appropriate approvals (i.e. IRB, IACUC etc.) must be obtained prior to the start of the research thesis year.**

Communicate early and often with all thesis committee members and thesis advisors regarding research progress and any areas of concern.

Ensure that thesis committee meetings are held at the 1, 3 and 6 month milestones and that a defense is scheduled no earlier than the final month of the research thesis year and no later than three months after completion of the research year or by December 15th, whichever occurs earlier unless otherwise exempted by the REC. It is the student's responsibility to ensure that meetings are held, that each committee meeting is attended by ALL committee members and that the meeting reports and any assessments are submitted to the CCLCM Research Office promptly.

Submit the final revised thesis within two weeks of defense. Ensure all defense documents are completed by committee within four weeks of defense.

Thesis Advisor Responsibilities

Time Commitment

- 1. Guide the student in developing a feasible and appropriate thesis project
 - Formulate a specific research question, identify appropriate methods to address the question, and develop a research plan and timeline
 - Assist the student in obtaining necessary approvals to complete the thesis project such as IRB or animal use protocols. If the student will be working under a previously approved protocol then confirmation stating the student has been named as a participant on the study must be submitted to the CCLCM Research office.
 - Work with student to select a thesis committee including a basic scientist and clinical researcher knowledgeable in the area of the student's research, and identify the chair of the committee
- 2. Oversee and assess student performance during the research project
 - Assist student in addressing challenges arising during research
 - Guide student in preparing for presentation of research to the thesis committee
 - Provide regular feedback to student regarding research skills and research progress
 - Complete two assessments of the student's performance during the research thesis. Assessments are due at the midpoint (6 months) and at the end of the project (12 months) and will be completed electronically via a link sent from CCLCM Portal. The 12 month / final assessment is due within four weeks of the defense. This information will be included in the student's portfolio for review by the Medical Student Promotions and Review Committee (MSPRC).
 - If at any time, there is concern that the student may not be appropriately progressing, notify the student's Physician Advisor and the chair of the Research EducationCommittee.
- 3. Attend all meetings of the student's thesis committee.

Committee meetings should be held in the first month of thesis work, 3 months into the thesis work, midway into the students' research project (6-9 months) and at the completion of the thesis (12-15 months).

Mentoring

- 1. Provide a supportive research environment
 - Spend sufficient time with trainee
 - Provide structure and support with regular meeting of research group
 - Reward excellence by recognizing it
- 2. Promote collaboration and networking on behalf of student
 - Facilitate interaction with other researchers, on site and in the wider professional community
 - Encourage participation in professional meetings
- 3. Guide and serve as a role model for upholding the highest ethical standards

Financial Commitment

Thesis advisors are expected to cover any costs directly associated with research (such as staffing, supplies, or reagents) but are not required to provide a stipend.

Thesis Committee Chair Responsibilities

All students within the Cleveland Clinic Lerner College of Medicine will complete a substantive research project under the guidance of a thesis advisor. The thesis advisory committee is responsible for the direction and guidance of that thesis work, and to ensure that the student meets the standards for research.

The Thesis Committee Chair will have the following responsibilities:

1. Lead and report on meetings of the student's thesis committee. The student is expected to schedule meetings within the first month of the project, at 3 months, at the midpoint (6 months) and at the end of the project (12 months/defense). After each meeting, the chair will complete a committee meeting report form electronically via a link sent from CCLCM Portal documenting the date and time of the meeting, names of all in attendance, a summary of the student's presentation and subsequent discussion, a list of goals for the following meeting as well as identify areas of strength or targeted areas for improvement.

At each meeting, the committee should address the following:

Has the student put intellectual energy into their project to date? Is the student's hypothesis or goal of the research project clearly stated and mechanistically oriented? Is the student's methodology clearly defined and understood? Is the student following appropriate laboratory and /or clinical standards? Is the student documenting his/her progress? For example, is the student maintaining a legible laboratory notebook?

Additional meetings can be scheduled at the discretion of the committee or the REC.

- 2. Within 4 weeks of the final thesis committee meeting (defense), complete a Committee Meeting Report form and the Thesis EvaluationForm.
- **3.** In the event that concerns arise about a student's progress on the thesis, contact that student's Physician Advisor as early as possible for intervention. The Physician Advisor is the student's impartial reviewer of academic progress throughout the CCLCM program. Contacting the PA is not punitive in any way, and can only benefit the student. Either the student or the Research Office can supply the name of that person.

Research Education Committee Monitoring of Progress

The Research Education Committee will assign one of its members to monitor the progress of each student's research thesis. The responsibilities of the REC monitor will include

1. Review of the cumulative evidence toward the research competency compiled during the research thesis which includes:

1 month time-point:

- Student's written thesis proposal (1 page with hypothesis and specific aims)
- Thesis Committee Meeting Report from the committee chair

3 month time-point

- Student's written thesis plan (5 page full plan with references)
- Thesis Committee Meeting Report form completed by committee chair

6 month time-point

- Student's written thesis progress report (highlighting any changes in direction or approach since 3 month thesis plan)
- Thesis Committee Meeting Report from the committee chair
- Thesis advisor's 6-monthassessment

12 month time-point

- Draft of written thesis
- Attendance at the thesis defense (if feasible)
- Thesis Committee Meeting Report from the committee chair
- Thesis advisor's 12-month assessment
- Thesis Project Completion Report to verify all named thesis committee members have signed off on final revised version
- Thesis Evaluation Report from the committee chair
- 2. It is the responsibility of the student to follow up and ensure that all documents are directed to the CCLCM Research Office in a timely manner. If any document is not received as expected, the Research Office will send a reminder to the student. If no response is received within five working days, the Research Education Office will contact the student and/or the thesis advisor, the thesis committee chair, and physician advisor.
- 3. Any concerns about a student's progress or ability to demonstrate achievement of the research competency or function of the thesis committee should be discussed with the mentor and/or committee chair. Unresolved concerns will be referred to the Research Education Committee for discussion. Concerns that cannot be adequately addressed within the REC will be referred to the Associate Dean for Student Affairs.

Standard Operating Procedure during Thesis Research

The table below outlines milestones within the thesis year, documentation that should happen at each step, and the person responsible for completing each task.

Timepoint	Documentation	Person responsible to complete	
6 to 12 months prior to research start	Fellowship/Grant Applications	Inform the CCLCM Research Office about all applications submitted for fellowship and grants. Failure to do so may result in the initiation of a referral to the MSPRC for unprofessional behavior	
6 months prior to research start	Thesis Project Information form NIH biosketch (including funding history) for each committee member One-page project description to include a title, relevant background information, need for the type of work being proposed, an overarching hypothesis, 2-3 specific aims, study design (including pertinent features – controls and power analysis if applicable), analysis plan, potential problems, feasibility of the study (time line) and appropriate approvals (i.e. IRB, IACUC). Funding of Student Research form Clinical Activity during Research Year form IRB or IACUC protocol numbers as applicable (or notification of pending status) IRB / IACUC must be submitted and approved prior to starting research	Student to complete and submit all forms and documents to the CCLCM Research Office electronically via the Electronic Forms link on the CCLCM Portal	
Upon notification of funding award	Copy of award letter IRB or IACUC approved protocol numbers if not already submitted Approval required prior to starting research	Student to submit copy of award letter to the CCLCM Research Office at <u>cclcmresearcheducati@ccf.org</u> and the Dean of Student Affairs.	
Upon research start	IRB or IACUC approved protocol numbers if not already submitted confirming student is named as a study participant IRB / IACUC must be submitted and approved prior to starting research	Thesis requirement must be completed as a contiguous year beginning on a Monday, ending on a Friday, and corresponding to dates of registrar's 2-week rotation blocks. Any change from this pattern must be pre-approved in writing by the REC. Contact all thesis committee members to schedule a meeting of the thesis committee to occur no later than one month into project	
1 month from research start	Thesis committee meeting	Student to ensure thesis committee meeting is held by one-month milestone and attended by ALL committee members. Student to identify date for 1 month meeting in Thesis Tracker. Student to circulate one-page research plan to all thesis committee members and upload the plan to the Thesis Tracker.	

1 month from research start	Thesis Committee Meeting Report	Thesis committee chair to complete and submit electronically to CCLCM Research Office Student to follow up and ensure report is submitted to CCLCM Research Office within one week of meeting CCLCM Office will forward copy to REC monitor	
3months from research start	Five-page full thesis plan and progress report	Student to prepare in consultation with the thesis advisor Student to distribute to thesis committee members before 3 mo. meeting Student responsible to upload the five-page research plan to the Thesis Tracker. CCLCM Office will forward copy to REC monitor	
	Thesis Committee Meeting Report	Student to ensure thesis committee meeting is held by three-month milestone and attended by ALL committee members. Student to identify date for 3 month meeting in Thesis Tracker. Chair to complete report and submit electronically to CCLCM Research Office CCLCM Office will forward copy to REC monitor	
6 months from research start	Thesis progress report	Student to report progress on thesis to date. Highlight any changes in direction or approach from 3-month thesis plan Student to distribute to thesis committee members prior to 6 mo. meeting Student responsible to upload the progress report to the Thesis Tracker CCLCM Office will forward copy to REC monitor	
	Thesis committee meeting	Student to schedule early enough to ensure meeting is held at 6-month time point and attended by ALL committee members. Student to identify date for 6 month meeting in Thesis Tracker.	
	Thesis Committee Meeting Report	Thesis committee chair to complete and submit electronically to CCLCM Research Office Student to follow up and ensure report is submitted to CCLCM Research Office within one week after meeting CCLCM Office will forward copies to REC monitor	
	Thesis Advisor's Assessment	Thesis advisor to complete and submit electronically to CCLCM Research Office Student to follow up and ensure report is submitted to CCLCM Research Office within one week of 6-month timepoint CCLCM Office will forward copy to REC monitor	

12 months from research start	Expected research completion date	Any changes to the schedule of thesis research activities including additional months of research elective must be approved in advance by the REC. Student to document any research electives using the Research Elective form available electronically on the Portal and have approved by the CCLCM Research Office.	
14.5 months from research start, no later than Dec. 1 of final year	Thesis (The copy submitted at this time should be a finished product with only minor editing changes as requested by the committee at the defense.)	Student to circulate to thesis committee members and CCLCM research coordinator two weeks prior to final thesis defense. There should be no changes to this document until after the defense. The copy submitted at this time should be a finished product with only minor editing changes as requested by the committee at the defense. Student to upload copy of proposed final Thesis Tracker.	
	Thesis defense and final committee meeting schedule confirmed	Student to notify CCLCM Research Office of date, time, and location at least two weeks in advance so meeting can be publicly announced.	
15 months from research start No more than 3 months after thesis research completed No later than Dec. 15 of final year	Thesis defense and final committee meeting held	Student to schedule early enough to ensure meeting is held no later than 3 months after thesis research is completed and no later than December 15 of year 5, whichever is earlier. Thesis presentation and defense meeting must be held on the same date, back to back. Any deviation from this timeline must be approved by the REC.	
Two to four weeks after thesis defense No later than 16 months from research start No later than Jan 15 of student's final year	Thesis Committee Meeting Report	Thesis committee chair to complete and submit electronically to CCLCM Research Office within four weeks of defense Student to follow up and ensure report is submitted to CCLCM Research Office within one week of meeting	
	Final revised thesis (no later than Jan. 1 ^{st)}	Student to complete revisions no more than two weeks after final thesis committee meeting, and no later than Jan. 1 st of final year and circulate to all thesis committee members. Student to submit electronic copy as a single PDF and a hard copy (no formal binding required) to CCLCM Research Office no later than two weeks after final thesis committee meeting, and no later than February 1 of year 5, whichever is earlier Only for students in the Biomedical Engineering dual degree, student to submit electronic copy to OhioLink or hard copy to Graduate School with optional petition to delay publication of thesis	
	Thesis Advisor's Assessment	Thesis advisor to complete and submit electronically to CCLCM Research Office within four weeks of defense Student to follow up and ensure report is submitted electronically to CCLCM Research Office within two weeks of final thesis submission	
	Thesis Evaluation form	Thesis committee chair to complete and submit electronically to CCLCM Research Office after reviewing final thesis revisions. No later than four weeks after defense. Student to follow up and ensure form is submitted to CCLCM Research Office within two weeks after final thesis submission	

	Thesis Requirement Completion form	All committee members sign form electronically signifying acceptance of student thesis within four weeks of defense.
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Timeline for Information Submission

The Curriculum Steering Council believes that insights gained from clinical experience can serve to enhance the research perspective of student investigators. Therefore, it is recommended that students begin Thesis Research at the beginning of their fourth year. It is recognized, however, that circumstances may arise in which a student may choose to initiate their research project prior to beginning third year clinical rotations.

All students are required to complete the thesis research year as a contiguous year (52 week block) that includes four weeks of vacation. Exceptions will be considered by petition to the REC on a case by case basis.

Students should submit a complete Thesis Project Information Form under electronic forms on the Portal, upload a NIH biosketch for the thesis advisor and all committee members as well as a project description to include a title, relevant background information, need for the types of work being proposed, an overarching hypothesis, 2-3 specific aims, study design including pertinent features – controls, power analysis if applicable, analysis plan, potential problems, feasibility of the study (time line) and appropriate approvals (i.e. IRB, IACUC). Ideally this information should come the REC 6 months prior to the anticipated start date of their research project. **IRB / IACUC must be submitted and approved prior to starting research.**

For those students who participate in a fellowship program at the NIH the REC recognizes that thesis advisors and projects will be determined after the program begins. Within the first month, students must submit the Thesis Project Information Form identifying the thesis advisor, basic and clinical scientists (of which one will serve as committee chair) and upload a project description. Members of the thesis committee (with the possible exception of the thesis advisor when the research is done at another institution) should all be located in the Cleveland area

By the end of the first month of research, a one page description of the thesis project plan should be circulated to members of the thesis committee. This plan should include sufficient background to understand the project rationale, a clear hypothesis statement, and methods that will be used to address the hypothesis. The Thesis Committee should discuss the plan, and modify if necessary to approve at the 1 month thesis committee meeting.

Thesis committee meetings should be held at the outset (1 month), at three months, midpoint (6 months), and at the completion of the thesis work (defense). Additional meetings may be scheduled throughout the year at the discretion of the thesis committee or the REC. Prior to each meeting the student should submit the appropriate research document to their committee and upload it to the thesis tracker.

The final thesis should be circulated to all thesis committee members as well as CCLCM Research Office at least two weeks prior to the defense. In consideration of thesis committee members and the REC, there should be no changes to this document until after the defense. The version submitted should be a finished product with only minor editing changes as requested by the committee at the defense.

- No more than 3 months after the completion of thesis research
- No later than December 1st of the fifth or final year of medical school
- No less than 2 weeks before the final thesis committee meeting or "defense"

The Research Office (<u>cclcmresearcheducati@ccf.org</u>) should be notified of the scheduled time, date and location of the thesis defense at least two weeks in advance.

A final revised thesis is due to the thesis committee within two weeks of defense and the final approved thesis is due to the Research Education Office within four weeks of the defense.

Funding during Research

All thesis research rotations are to be done at the Cleveland Clinic, Case Western Reserve University or an affiliated institution. Only students that have been awarded a NIH, Doris Duke, Fulbright or Sarnoff fellowship, who are not in remediation, will be permitted to complete their research year outside of Cleveland. Since Thesis Advisors are expected to cover all costs directly associated with research but are not required to provide a stipend; students may apply for research fellowships from other funding sources (e.g. HHMI, AHA, AOA) that can be used to support their research year in Cleveland.

Students are to notify the CCLCM Research office of every fellowship and grant applied for prior to submitting their application to the sponsor. They are also to inform the Research Office once notification of the award decision has been received. Failure to do so may result in the initiation of a referral to the MSPRC for unprofessional behavior.

Notes for Students Completing the Thesis Requirements Away from Cleveland

Students are expected to complete the thesis requirement within the network of CWRU-affiliated institutions in Cleveland, Ohio. An exception is made for students who have been accepted to the NIH Medical Research Scholars Program (MRSP) or been awarded a Doris Duke, Fulbright, or Sarnoff fellowship who are not in remediation. In that event, it is the responsibility of the student to:

- 1. Obtain advance approval of the proposed thesis mentor and the membership of the thesis committee by the Research Education Committee. Requirements are outlined in the Thesis Plan Submission Process section of this handbook. The one exception is for students in the NIH-MRSP because the student will not know the name of the mentor or the project details until after relocating.
- 2. Contact the sponsoring institution for their specific requirements before starting. Typical examples include
 - a. proof of medical malpractice liability insurance from the medical school registrar
 - b. proof of HIPAA and OSHA compliance from COMET (transcript with completion/expiration dates)
 - c. proof of immunizations from the CWRU University Health Service
 - d. proof of the student's own health insurance from the CWRU University Health Service, or the alternate insurance provider if student insurance was waived
 - e. arrange stipend payments

Please note that all other requirements are identical to students staying in the Cleveland area. The student is still registered as a full-time medical student through CCLCM to earn research credit as well as to maintain health and malpractice coverage as noted above.

Students are still limited to 3 credit hours of coursework per semester. Tuition for individual courses at outside institutions will not be covered by CCLCM. Contact the office of financial aid if assistance for outside tuition is desired.

The thesis committee will be constituted by faculty located in Cleveland, Ohio. Other faculty may be listed as consultants, but will not formally serve on the thesis committee.

Please note that students who are remediating any milestone of any competency (not limited to the research competency), or who for any reason are not considered a student in good standing at CCLCM, will not be permitted to complete the research thesis year away from Cleveland, Ohio or to apply for funding from those programs (NIH, Doris Duke, Fulbright and Sarnoff).

Thesis Plan Submission Process

1. Identify a thesis advisor and the focus of the research project

All thesis advisors must to be approved by the Research Education Committee (REC). If a student selects an advisor that has not worked with year-long research students in the past, the prospective advisor's NIH biosketch and a one to two page project description (including the following: a title, relevant background information, need for the type of work being proposed, an overarching hypothesis, 2-3 specific aims, study design (including pertinent features – controls and power analysis if applicable), analysis plan, potential problems, feasibility of the study (time line) and appropriate approvals (i.e. IRB, IACUC) needs to be submitted to the Research Education Office. Note that in most cases, thesis advisors will be limited to a single student for the year of research.

Thesis advisors participating through NIH or similar fellowship programs will obviously be acceptable, but an NIH biosketch is required for program records.

Identify a thesis committee with assistance of the thesis advisor. Members of the thesis committee (with the possible exception of the thesis advisor when the research is done at another institution) should all be located in the Cleveland metro area and cannot have a direct reporting relationship to the mentor. Members at the Cleveland Clinic should rank at the Assistant Staff, Associate Staff, or Staff level; they should also hold an active academic appointment at any level in the Cleveland Clinic Lerner College of Medicine. Thesis committee members at CWRU-affiliated institutions other than the Cleveland Clinic should rank at the Assistant Professor, Associate Professor, or Professor levels. In the case of research to be done at another Institution, it is recognized that the thesis advisor will usually not have an academic appointment at the CWRU School of Medicine.

The minimal committee composition should include:

- a. Thesis advisor
- b. Clinician Investigator (M.D. or equivalent) knowledgeable in the area of research. Cannot have a direct reporting relationship to the mentor
- c. Basic scientist researcher (Ph.D. or equivalent) knowledgeable in the area of research. Cannot have a direct reporting relationship to thementor.
- d. Other members as needed to provide a spectrum of expertise, an outside perspective, or to represent the student's graduate program

The chair (either the clinical or basic scientist) of the thesis committee should have expertise in the area of the thesis. The thesis advisor will not personally serve as the chair. The Physician Advisor may attend the thesis committee meetings at their option as a nonvoting member.

If the student is interested in obtaining a graduate degree based on a CCLCM – CWRU thesis, the student should refer to specific guidelines for the advanced degree.

2. Complete the Thesis Project Information Form available electronically on the Portal and upload all supporting documents (NIH biosketch for all committee members and one page project description) for review by the REC.

The student's thesis advisor and thesis committee should be selected 6 months prior to the start of the thesis work

IRB / IACUC must be submitted and approved prior to starting research.

3. Complete the Funding of Research Form via Electronic Forms under Resources on the Portal. Thesis Advisors are expected to cover any costs directly associated with research but are not required to provide a stipend.

When all forms are complete and supporting documents received, the proposal will be reviewed by the Research Education Committee. Students will be contacted when project is approved or if the REC has any questions/concerns that need to be addressed by the student before approval can be given. All students must receive REC approval prior to starting research thesis with the exception of students at the NIH.

Clinical Requirements during Research Block

Students are required to participate in clinical activity for an average of one half-day per week while on their research blocks. Students are encouraged to select clinical experiences that are aligned with their research project. This experience is part of the research block and does not represent a separate clinical rotation. Therefore, this does not count toward the graduation requirement for weeks of clinical activity.

The goals of the clinical experience during the research block are to:

- 1. Strengthen the clinical perspective of the research project.
- 2. Maintain clinical skills including history, physical examination, clinical reasoning (diagnosis and management).
- 3. Emulate the responsibilities of physician investigators who balance clinical responsibilities with research.

Requirements:

- 1. The clinical experience should average one-half day per week during the research block.
- 2. Students are encouraged to spend some clinical time in an area related to their research. Such activities might include:
 - a. Conducting a clinical research project in which history taking and/or physical examination is required.
 - b. Participating in clinical activities with the clinical research preceptor for the student's project.
 - c. Arranging for a clinical experience in a discipline related to the research project
- 3. Students may work with more than one preceptor but must identify a "primary preceptor", a faculty member with whom they will be working who will be responsible for assessing the student.
- 4. If a student is pursuing research prior to starting the Basic Core rotations, they should select a "primary clinical preceptor" in one of the areas listed below and arrange to work with that preceptor 1-2 times a month, alternating with a clinical experience related to their research project.
 - a. General Internal Medicine
 - b. Internal Medicine Subspecialty
 - c. Family Medicine
 - d. Pediatrics
- 5. Any proposed clinical activities not at CCF require an outline of student responsibilities and supervising physician contact information. Students may not have their entire clinical experience outside of CCF or CWRU, unless their research thesis work is not in Cleveland. *
- 6. The Assistant Dean for Clinical Education and Physician Advisor will review and approve the proposed clinical experiences.
- 7. Students should complete the Clinical Requirements during Research Block electronic form that is available on the Portal (under resources) and submit it prior to the start of their research. For students doing research away from Cleveland the form should be submitted no later than one month after starting their research.

Assessment:

- 1. Students will log at least one patient each week in CAS, regardless of preceptor or location.
- 2. For patients seen with their primary preceptor, students will send individual or bundled patient logs for assessment to that preceptor monthly in CAS. This feedback is formative to help the student improve. As this is not a separate rotation, no formal summative feedback is required.
- 3. Students not meeting the minimum requirement for clinical activity during research will be notified and expected to complete the Clinical Activity during Research form. This form will then be reviewed by the Assistant Dean for Clinical Education and the student's Physician Advisor to determine the appropriate next steps.

Your primary clinical preceptor will be sent an information packet outlining their responsibilities. For clinical preceptors outside of Cleveland this will include an orientation to CAS.

* Students completing research away from Cleveland fall under the same guidelines listed above. As part of the transition back to Cleveland, third year students doing research away from Cleveland may contact the Assistant Dean for Clinical Education to arrange for an optional week of clinical training at the Cleveland Clinic prior to starting Basic Core rotations.

Thesis Year Assessment

During the year of thesis research, the student will continue to accumulate assessments for their portfolio.

The following evidence should be collected during the research year:

- The thesis committee chair will complete a Thesis Committee Meeting Report after the 1 month, 3 month, 6 month and 12 month (defense) thesis committee meetings.
- The thesis advisor will complete two assessments the first at the midpoint of the project (6 months) the other at project completion (12 months).
- Documentation of thesis progress from the research year including
 - 1 Month Thesis Proposal
 - 3 Month Thesis Plan
 - 6 Month Thesis Progress Report
 - Finished thesis document
 - Powerpoint presentation from the final committee meeting and/or graduate department seminar
- Any publications, posters, or presentations
- Any fellowship or grant awards earned
- All Defense documents: Committee Meeting Report, Thesis Evaluation form, Final Thesis Advisor's Assessment and Thesis Requirement Completion form. Defense documents must be completed by the appropriate committee member within four weeks of the scheduled defense.

Thesis Tracker

The College uses a program that allows the Research Office to track student requirements during research thesis. Prior to each committee meeting students must access the "Thesis Tracker" located on the Portal under Resources and enter the date of their committee meeting and upload their written research plans/updates. Electronic versions of the Thesis Committee Meeting Report, Student Assessment during Research and all defense forms will automatically be sent to the appropriate committee member for completion.

Safe Contact for Student Concerns

If at any time a student feels they are being mistreated and are uncomfortable speaking with their thesis advisor or a member of their committee they should contact their Physician Advisor, Kathleen Franco, MD, Associate Dean, Admissions/Student Affairs, Linda Graham, MD. Assistant Dean, Research Education or Trine Jorgensen, PhD, Associate Director, Research Education.

Vacation during Research Year

The research year requires 48 weeks of active research time. Four weeks of vacation rounds out the year (total of 52 weeks). For all students <u>the four weeks of vacation needs to be taken as part of the research year commitment (52 weeks total</u>). Vacation time cannot be banked for future use, used for clinical rotations or prior to the research start date. Vacation time should include National holidays observed by the Clinic (Thanksgiving, Christmas Day, New Year's Day, Memorial Day, July 4th and Labor Day). For students completing research in their fifth year, vacation time must be used for interviews.

Deadline for Thesis Committee Meetings

Students, their thesis advisor, and thesis committee members will be notified by e-mail of approaching deadlines for thesis committee meetings and for the thesis defense. If students do not respond to the e-mail within one week with the meeting date or at least an acknowledgement of the requirement, a second e-mail will be sent to the student, copying the Physician Advisor. If no response is received, a third e-mail will be sent to the student, copying the Physician Advisor and the Associate Dean for Admissions and Student Affairs. If no response is received within 1 week, the MSPRC will be notified of the failure of the student to exhibit expected professional behavior.

If a required thesis committee meeting or the thesis defense cannot be held within 1 month of the required time, the student may petition the REC in advance for an extension of the deadline. The petition should include the factors necessitating a delay in the required meeting as well as a specific timeframe when the meeting will be held. In the absence of a REC-approved extension, failure to hold the meeting within 1 month of the required time will result in MSPRC notification of noncompliance with the research requirements.

Guideline for 3 Month Thesis Plan

By the three-month mark, each student will draft a formal thesis plan with input from their thesis advisor. This proposal should not exceed 5 double-spaced pages (not including references, IRB application, or IACUC application). This proposal should be reviewed by the thesis committee for feedback and approval prior to the beginning of the third month of research time allocation.

The 3-month Thesis Report will include the following:

- 1. A hypothesis driven research question
- 2. Background information
- 3. Study design with appropriate controls, as necessary
- 4. Research methods
- 5. Statistical design for analysis of data
- 6. For human studies, include a description of research subjects with appropriate inclusion and exclusion criteria
- 7. Completion of appropriate human research and/or animal research approval forms including informed consent document for human research
- 8. Identify limitations of the study in addition to potential difficulties and possible alternative approaches
- 9. Literature citations used forbackground

Guideline for 6 Month Progress Report

By the six-month mark, each student will draft a progress report with input from their thesis advisor. This report should be a progress update based on the 3-month plan. If any changes in direction or approach are necessary, these should be highlighted for the thesis committee. This report should be circulated for review by the thesis committee in preparation for the 6-month meeting.

Thesis Defense Scheduling

Students may schedule their defense to occur during the final month of the research year but are required to schedule their defense within three (3) months of finishing their research. The meeting is to be scheduled at a mutually convenient time for all committee members. All committee members, including the thesis advisor, must attend or the meeting will not be considered a defense. The defense should not be scheduled at a time that interferes with the student's clinical responsibilities.

If additional time beyond the three months is required, students may petition the Research Education Committee for an extension. The student must have a very compelling reason for the extension, provide a final date for the thesis defense and documentation from the thesis advisor and committee stating they support the student's request.

Final Thesis Structure

Some students will have published all or part of the thesis work. These publications will not suffice for a written thesis document. While a publication focuses on methods and results, the thesis should also include a broader view of the rationale behind the approach, the methods used, expected results (whether or not those results were obtained), failed experiments, and negative data. The thesis is intended to show the entirety of the work attempted and accomplished by the student during the research year.

The a copy of the final thesis should be provided to the thesis committee at least 2 weeks prior to the defense, no later than 2.5 months after research time is concluded and no later than December 1 of year 5. In consideration of the thesis committee and members of the REC, there should be no changes to this document until after the defense. The copy submitted at this time should be a finished product with only minor editing changes as requested by the committee at the defense.

The thesis document should be formatted as follows:

- Text should be double spaced in 12 point font in any standard typeface. Footnotes and endnotes may be single-spaced.
- The left margin should be 1.5 inches. Top, bottom, and right margins should be 1 inch.
- Page numbers for section headings, tables and figures should be included in the table of contents.
- Finished thesis should be 25-50 pages in length, including figures and tables, not including the cover page, table of contents, or bibliography.

The thesis should include the following components:

- 1. *Title Page:* Include thesis title in upper and lower case, student name, "Submitted for the M.D. degree from the Cleveland Clinic Lerner College of Medicine Program, Case Western Reserve University", month and year of graduation.
- 2. *Table of Contents:* Table of Contents pages should be numbered in lower case Roman numerals (i, ii, iii, etc.). The thesis document should be paginated so that the abstract begins on page 1. Figures and tables should be interspersed within the text (can be on adjacent pages) and should be included in pagination. Paginate the bibliography as well.
- 3. *Abstract:* A concise summary of the work with a limit of 350 words. Pagination should begin at 1 on this page.
- 4. *Introduction:* Provide pertinent background and review of the literature in regards to the general area of study and then focus on the specific problem investigated. State the hypothesis of the research or the specific question/problem being addressed.
- 5. *Methods:* Describe the research methods utilized at the level of detail that would allow an investigator to reproduce the study. Clinical studies should detail inclusion and exclusion criteria. Describe statistical methods used in analyzing data.
- 6. **Results and Conclusions:** Describe specific experiments and studies that were performed and summarize results. Include relevant figures and/or tables in this section. Figures and tables should be integrated within the text. Integration on the same page is not necessary, but this information should be contained on adjacent pages.
- 7. **Discussion:** Interpret the data and relate the results to the research question/hypothesis stated in the introduction. Discuss alternative interpretations of the data and limitations of the study. Compare findings to others in the field by citing appropriate literature. Discuss additional experiments that might resolve unanswered questions. Suggest future opportunities for research.

8. Acknowledgements

9. Bibliography: Provide appropriate references in a format acceptable for a scientific journal publication.

Agenda and Documentation for Final Thesis Committee Meeting

The final thesis committee meeting will be a thesis defense. The student will deliver a public, 30-50 minute oral presentation of the research project to the thesis committee and to the local research community. The student should be prepared to answer questions from the audience. Students doing research off-site may present their work from either that site or CCLCM, but the seminar should be open to the campus community. Thesis committee members at another site may participate by teleconference.

Agenda for CCLCM Thesis Defense:

- 1. The Mentor introduces the student to the public.
- 2. The student presents their thesis research orally in a presentation lasting 30-50 minutes.
- 3. The Thesis Committee Chair asks the public if there are any questions (committee members should not ask questions at this time).
- 4. The Thesis Committee Chair excuses the public from the room.
- 5. If the Chair has serious concerns about the thesis quality, the chair may ask the student to leave the room prior to the oral defense to discuss concerns with the committee. Usually this is not the case and the Chair commences part 2 after the public leaves the room.
- 6. The Chair asks each committee member in turn to ask questions for a period of up to 10 minutes each. After each member has taken their turn, the chair asks if any member wants a second round of questions for up to 10 minutes.
- 7. The student will be excused from the room. The committee will discuss the potential outcomes as described on the thesis evaluation form. At this time, all of the questions on the evaluation form should be discussed and the chair should write the consensus of the discussion on the form (to be completed electronically later).
- 8. The student will return to the meeting and the chair will summarize the committee's evaluation to the student.
- 9. Committee members will complete all defense forms within two weeks of submission of the final revised thesis or no later than 4 weeks after the defense.

The committee may ask for edits to the thesis. The student will have 2 weeks to edit the thesis and obtain approval of the final revision from the thesis committee.

The final written version of the research thesis document should be completed within two weeks of the thesis defense date, but no later than March 1 of the fifth or final year of medical school. One hard copy of the thesis and an electronic copy as a single pdf should be submitted to the Office of Research and Graduate Education at the two week mark, but no later than March 1 of year 5.

After revisions are complete, all members of the thesis committee will sign the Thesis Requirement Completion Form electronically indicating acceptance of the thesis within four weeks of the defense. The thesis committee chair will complete the Thesis Evaluation Form and Committee Meeting Report form electronically within four weeks of final meeting.

Dual Degree Option and Graduate Courses during the Thesis

Students have the option to apply to a variety of dual degree programs, combining the M.D. degree with a second degree such as a Master of Science (M.S.) or Master of Public Health (M.P.H.). Each dual degree program has its own unique course and thesis requirements (detailed in separate documents). These may include an additional project approval process, specific requirements about thesis committee makeup and meeting frequency, lists of required and elective coursework, and specific guidelines for written thesis submission and final presentations. Students are responsible to investigate and fulfill all requirements for both of the degree programs, and should make an effort to maximize the programs' overlap (to avoid the potential for multiple thesis committees, etc.). Early and continuous interaction with the Graduate Program Director for the relevant dual degree program/track is critical for a successful experience.

Application to a dual degree program, if desired, should be no later than August 15 of the second year. Be aware that **only six credit hours of coursework taken prior to application can be credited toward the degree without special petition**. Applications should be directed to the Research Office for assembly of all materials and forwarding to the appropriate program directors. This office also handles all registration for graduate courses.

During the thesis year, student may register for a limited number of graduate course credits. As a rule, students are permitted to register for 3 semester hours (4.5 quarter hours) in any single semester (or quarter). Exceptions to this limit will be considered on a case-by-case basis and ONLY with the advanced written agreement of the thesis advisor. Double-counted research and seminar credits are not included in the 3 hours per semester limit. Credit hour limits also apply to students doing research outside the Cleveland area. CCLCM will not cover tuition costs for outside courses, but financial aid may be available.

Students who receive a type A masters degree from CWRU are required to publish the masters thesis electronically on OhioLink. At this time, only the M.S. in Biomedical Engineering is subject to this requirement. Other masters programs (CRSP, pathology, nutrition, bioethics, and MPH) technically have "projects" rather than a thesis and cannot be published on OhioLink.

Additional questions regarding the dual degree programs should be directed to Dr. Dennis Stacey.

Electronic Publication of the Thesis

The graduate school of Case Western Reserve University requires that all **type A masters** theses be published electronically through OhioLink. At this time, only the Biomedical Engineering M.S. program is a thesis masters.

The thesis will be accessible in its entirety upon e-publication. In order to protect unpublished work or patents still pending, the thesis advisor may choose to delay this publication for up to two years from the date of submission to the graduate school. In order to delay publication, the thesis should be submitted on bond paper accompanied by the CWRU Request to Delay Release of Dissertation form, included in this handbook.

The deadline for electronic submission of the thesis (or submission of a paper copy with the Request Delay Form) is on page 25. Exact dates for each academic year can be found on the CWRU Graduate Studies website at http://www.case.edu/provost/registrar/calendars/5year.html

Case Western Reserve University Request to Delay Release of Dissertation

Student Name:
Student ID#:
Department:
Date of Graduation:
Dissertation Title:

Reasons for delaying the electronic submission of a dissertation:

- 1. The student is in the process of applying for a patent on the research contained in the dissertation and does not wish to make its contents public until the patent application has been filed.
- 2. The student wishes to publish the dissertation as a book or a journal with a publisher whose policy is not to publish anything that has already been disseminated electronically.

Student and Committee Agreement:

My advisory committee and I agree that the above-mentioned document be held for release for the following amount of time:

10. 6 MONTHS
11. 1 YEAR
12. 2 YEARS

At the end of the selected time, your dissertation will be released to both OhioLink and UMI/Proquest. If it becomes necessary, the student may request, by way of petition, for additional time.

Return completed form to Penny Thompson at <u>thompsp@ccf.org</u> or the Office of Research and Clinical Education in NA2-05 (mailcode NA20)

Guidelines Contact List

For general information about thesis issues:

Linda Graham, MD	Assistant Dean, Research Education	(216) 445-3298	grahaml@ccf.org
Trine Jorgensen, PhD	Associate Director Research Education	(216) 444- 8181	jorgent@ccf.org
Penny Thompson	Research Thesis Coordinator	(216) 444-0673	thompsp@ccf.org

Appendix A:

Teacher-Learner Relationship (casemed.case.edu/student_affairs/handbook/teacher_learner.cfm)

Expectations of Faculty and Students in the Teacher-Learner Relationship to foster the Learning Climate of the CWRU School of Medicine

An underlying principle of the medical school is that students and faculty will work together as partners to ensure that every student achieves his/her fullest potential and succeeds in the educational program.

We as faculty - physicians, researchers, residents, fellows, and other health care and research professionals - are committed to treating our students as our professional colleagues who, like faculty members, will exercise privileges and responsibilities throughout their education.

We expect students and faculty to demonstrate respect for others by upholding a classroom atmosphere conducive to learning, interacting in a considerate and cooperative manner with other students and faculty, judging colleagues fairly, and attempting to resolve conflicts with respect for the dignity of others. We expect students and faculty to neither practice nor tolerate discrimination on the basis of race, religion, age, sex, color, disability, sexual orientation, gender identity or expression, national or ethnic origin, political affiliation, status as a disabled veteran or other protected veteran under US federal law, or socioeconomic status.

We expect students and faculty to demonstrate responsibility by striving for excellence and professional growth, by recognizing their own limitations and seeking help when needed, by avoiding the use of alcohol and other drugs in a way that could interfere with clinical or educational responsibilities, by seeking frequent constructive feedback on their interactions with one another, and by conducting themselves professionally at all times in demeanor, language and appearance in the classroom, with patients, and in health care settings.

We expect faculty to commit their time and effort to ensure appropriate delivery of an interactive curriculum. We expect students to attend all sessions for their own learning, to enhance the learning environment for their peers, and out of respect for faculty effort.

We expect teachers and students to demonstrate respect and professional concern by holding each other to the highest standards in learning, without abuse, humiliation or harassment of any kind, by not exploiting a relationship for personal gain or advantage, and by demonstrating the highest standards of ethical conduct in all settings.

Mistreatment arises when behavior shows disrespect for the dignity of others and unreasonably interferes with the learning process. Examples of mistreatment include public belittlement or humiliation, threats of physical harm or punishment, inappropriate requests to do personal services (shopping or babysitting), sexual harassment, and discrimination or harassment based on race, religion, ethnicity, gender, or sexual orientation.

Neglect might be used to describe situations in which a student is openly ignore, is excluded from important decisions, or made to feel "invisible." Neglect is different from overt mistreatment but can still interfere with the learning process.

Harassment, mistreatment and neglect policies are discussed at new student orientation, orientation to year 2, and again prior to starting clerkships. If a student feels that he or she has been harassed, mistreated or experienced neglect during the conduct of the curriculum, and is uncomfortable addressing this directly with the colleague involved, we urge the student to discuss his/her concerns as soon as possible through one of the options detailed below.

- Students in any phase of the curriculum may address their concerns with the course or clerkship director, or Assistant Dean charged with that phase of the curriculum.
- Students in any phase of the program are strongly encouraged to bring the matter to the attention of their Society Dean, Dean of Student Affairs, or their Physician Advisor, or because the deans work as a group practice, students may choose to speak to another Student Affairs dean if they feel more comfortable doing so.
- Alternatively, students have the option of contacting Dr. Patricia Thomas, School of Medicine Vice Dean for Medical Education, <u>pat30@case.edu</u>, or G. Dean Patterson, Jr., Associate Vice President of the University Office for Student Affairs. The University Student Affairs office is not part of the medical school administration. Students can e-mail Mr. Patterson at <u>gdp2@case.edu</u> or call the office at 216.368.2020 to make an appointment. The office is located at 110 Adelbert Hall on Adelbert Road.
- Online Reporting: Both the University and College programs have established an online "Early Concerns" reporting mechanism, by which students can report experiences of harassment, mistreatment or neglect. These reports are confidential *but not anonymous* and will be reviewed by the appropriate Student Affairs dean. The Early Concerns report is available on the ecurriculum (http://case.edu/medicine/faculty-staff/ecurriculum-resources/).
- Box Reporting: Both the University and College programs have established a hardcopy reporting system. Boxes to leave these reports are located outside SOM E-405 and on the CCLCM campus at NA2-90 (Student Lounge). These reports are confidential and will be reviewed by the appropriate Student Affairs dean. Note: Without specific information, the School may be limited in its ability to respond to the report.

What Happens with a Report?

All reports are handled confidentially, and wherever possible, de-identified information about the event is used. The School of Medicine is obligated to follow federal guidelines (Title IX) for reporting sexual misconduct. For other situations, the Society Dean or Associate Dean of Student Affairs will pursue the report as follows:

- 1. Reports are collected by medical school staff in the Offices of Student Affairs.
- 2. If known, the reporting student will be contacted by Student Affairs Dean, basic information verified, and additional information requested if needed.
- 3. The report is logged in the Office of Student Affairs on the University's Log of Student Complaints.
- 4. If appropriate, the report is redirected to University Office of Student Conduct (ie Title IX).
- 5. A de-identified report is reviewed by the Student Affairs Dean with the appropriate curricular leader.

Depending on the judged severity of event and timing related to grades and evaluation, the Student Affairs Dean may to determine any of the following is appropriate:

- Report is shared with the professional involved
- Report is shared with course director, clerkship director and/or program director
- Report is shared with the professional's supervisor
- Report is shared with department chair (in the case of a faculty member)
- Report is shared with Dean
- Report is shared with Office of Faculty Affairs

When deemed appropriate the professional and his/her supervisor are asked to create an action plan that is shared with the Society Dean or Student Affairs Dean.

The Society Dean or Student Affairs Dean will post an incident report summary including outcome to the ecurriculum or student portal (without any identifying features) and if known, sent to the student who submitted the report.

Unprofessional behavior with learners that is severe or repeats despite feedback will result in removal from the teaching program and may be cause for learners' dismissal from their degree program or faculty members' termination for just cause as provided in the CWRU Faculty Handbook.

Aggregated Reports

The School of Medicine reports aggregated de-identified data on learner mistreatment to each department chair and the Dean on a quarterly basis.

Discussion/Reporting Resources:

- Your Society Dean, Student Affairs Dean or Physician Advisor
- Pat Thomas, Vice Dean for Medical Education: pat30@case.edu
- G. Dean Patterson, Associate Vice President of the University Office for Student Affairs: <u>gdp2@case.edu</u>
- <u>Sexual Misconduct Policy</u>
- Bias Reporting System(BRS)

Approved by the Committee on Medical Education 7/23/15.