MEDICAL STUDENT RESEARCH PROGRAM and the YALE MD THESIS REQUIREMENT



Yale school of medicine

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OVERVIEW AND HISTORY OF STUDENT RESEARCH AT YALE SCHOOL OF MEDICINE

The Yale System of medical education is designed to foster critical judgment, acquisition of knowledge, and commitment to improving the health of all persons and communities through the habits of selfeducation, imagination, and scholarship. Central to these goals is research skill development, which enables Yale students to ask and answer questions according to the high standards of research ethics and methodologic rigor befitting the physician's role in patient care. To develop the abilities needed to advance medical knowledge, YSM medical students participate in a research curriculum throughout their time at Yale. The final assessment of students' mastery of research-related curricular objectives occurs through a dissertation-style thesis ("MD thesis") reporting original, health-related research conducted under the supervision of YSM faculty member during medical school. Presentation of a thesis has been one of the requirements for the degree of Doctor of Medicine at Yale for over 180 years. Initially, case reports and literature reviews predominated, but as the scientific method was established in medicine, the faculty required that dissertations presented be based on original investigation conducted in laboratory or clinical realms. The first evidence that the thesis was required for Yale's MD degree is in this statement from the 1839 catalog: "...the candidate must present a dissertation on some subject connected with the medical sciences." YSM's research curriculum has evolved to culminate in the submission of a written thesis as an assessment of research competencies in partial fulfillment of graduation requirements. In its present form the thesis continues to flourish and is enthusiastically endorsed by students, faculty, and alumni as a central component of the "Yale System" of general medical education.

To this day, YSM continues the tradition of required medical student research, broadly defined as the creation of new knowledge through the generation and/or analysis of data. The creative discipline required to conduct an original research project and prepare a thesis enables each student to become a physician-scholar, whether their ultimate career objective is research, clinical practice, education, administration, industry, advocacy, or activism. The YSM research curriculum teaches students how to ask and answer questions according to principles of the scientific method in order to: critically appraise existing evidence in order to establish a strong premise for their projects; specify a clear, impactful, and innovative research question; collect and analyze data in a rigorous, responsible, and ethical manner; and clearly communicate research findings in written, spoken, and digital forms to maximize their impact for communities of interest. As such, the completion of the YSM research program and thesis will prepare students to ask and answer questions for the rest of their professional lives.

OFFICE OF STUDENT RESEARCH

The MD student research program is housed in the Office of Student Research (OSR) and is led by two associate deans, Dr. Sarwat Chaudhry, MD, Professor of Medicine (General Internal Medicine) and Dr. Erica Herzog, MD, PhD, John Slade Ely Professor of Medicine (Pulmonary) and Pathology. OSR exists within the Department of Medical Education under the governance of the Deputy Dean for Medical Education and Educational Policy and Curriculum Committee (EPCC) with which it collaborates to develop strategic vision and achieve pedagogical goals. Practically, OSR oversees all aspects of YSM MD student research including, but not limited to: 1) organization of research courses during the MS1 year; 2) guiding students in the process of identifying potential mentors and projects; 3) administration of funding applications and payments; 4) overseeing the approval of research projects; 5) coordination of thesis approval in fulfillment of the partial requirement for the granting of Yale's MD degree; 6) obtaining external support, including from NIH, for support of student research; 7) overseeing the fulfillment of Responsible Conduct of Research training; 8) administering the Master of Health Science degree program; and 9) providing guidance to students and mentors experiencing research challenges.

OSR is supported by a Deputy Director for Scientific Affairs, Dr. Alexandra Hajduk. Office functions are administered by the Associate Director and a team of support staff. OSR is highly accessible to students, mentors, and the YSM community and maintains communication via email to facilitate questions related to medical student research and the thesis requirement. Deans Chaudhry and Herzog offer weekly office hours during scheduled time blocks (Chaudhry: Wednesdays from 12-1; Herzog: Tuesdays 12-1) or at other times through scheduled appointments. These office hours are an excellent opportunity for personalized discussion of research related topics including but not limited to projects, mentors, challenges, and career pathways. Office hour appointments can be made by contacting the OSR email address (see below). Emails to OSR staff and leadership are also welcome. Contact information is as follows.

OSR Contact Information

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OSR Leadership

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OSR Administrative Staff

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Ms. Kelly Jo Carlson, Senior Administrative Assistant: kellyjo.carlson@yale.edu

Departmental Thesis Chairs

OSR's mission is executed by the "Departmental Thesis Chair Committee." These individuals play a critical role in the cultivation and management of YSM's student research enterprise. While their title denotes their contributions to the thesis process, Thesis Chair responsibilities involve numerous OSR functions including: 1) supporting students in their mentor search; 2) provision of feedback on students' research funding proposals; 3) approval of short term and/or summer research funding requests prior to OSR submission; and 4) approval of applications for one-year research funding prior to OSR submission. During the fourth year of medical school, when the student prepares the required thesis, Departmental Thesis Chairs perform critical functions including: 1) communication with students regarding departmental deadlines for thesis submission and review; 2) consideration and granting of deadline extensions; 3) coordination of the departmental thesis review and approval process; 4) review and approval of all theses submitted in a given department. Given their close working relationship with students, Departmental Thesis Chairs provide invaluable insights to OSR leadership. Drs. Chaudhry and **Yale SCHOOL OF MEDICINE Office of Student Research** 5/39

Herzog meet with and communicate with this group regularly over the course of the academic year. The 2023-2024 Departmental Thesis Chairs can be found <u>here.</u>

MEDICAL STUDENT RESEARCH PROGRAM AT YALE

Overview

Students appreciate that unexplained pathophysiologic and clinical observations, as well shortcomings in the provision of patient-centered healthcare, can inspire research that advances the practice of medicine. As such, they perform mentored scholarly research in these realms culminating in a formal thesis. This process promotes understanding of the scientific method and contributes to new medical knowledge/practices. The YSM research curriculum promotes the development of these skills though the educational program objectives presented below. Student progress is evaluated through milestone-based assessments throughout the pre-clerkship years and advanced training period (ATP), and culminates in the writing of the thesis during the fourth year of medical school.

Medical Student Research Educational Program Objectives

Objective 1: Critically evaluate and use literature, databases, and primary sources to develop a strong scientific premise for a research question, apply the scientific method to ensure robust, reproducible, and unbiased study design.

Milestones:

- By the end of the pre-clerkship phase, students are expected to be able to perform a well-directed literature search to access primary sources which support the framing of a research question and, with close supervision from a faculty mentor, writes and submits proposal aimed at answering a research question.
- During the early ATP, students are expected to develop initial research questions and study design informed by gaps in scientific knowledge and principles of scientific rigor and reproducibility. They should be able to incorporate feedback from faculty mentor to improve and refine their initial research plan.
- By the late ATP, the student is expected to demonstrate growing independence and develops and refines initial research questions and study design informed by gaps in scientific knowledge and principles of scientific rigor and reproducibility. With their mentor, they should be able to recognize and overcome methodologic challenges in study design, identify major threats to internal and external validity, and develop plans to mitigate any shortcomings.

<u>Objective 2:</u> Rigorously analyze and interpret data using appropriate scientific and statistical methods. Convey research findings in a clear and organized manner and disseminate to communities of interest.

Milestones:

- During the pre-clerkship phase, with faculty member supervision, the student is expected describe both quantitative and qualitative research methods to analyze data and how they might be used in various research designs and begins to share research plans and early findings with peers and scientific community.
- In the early ATP, the student recognizes and selects appropriate analytic methods for research

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questions, study designs, outcomes of interest and presents scientific findings in a clear and compelling manner.

• By the late ATP, the student can accurately depict and interpret results of analyses, acknowledging limitations; presents findings to communities of interest; anticipates and responds to questions, recognizes errors/limitations, and works with their faculty mentor to rectify these issues.

Objective 3: Apply principles of responsible conduct of research to preserve the integrity of the research process and to protect the privacy and rights of research subjects.

Milestones:

- During the Pre-clerkship phase, the student is expected to understand the principles of responsible conduct of research and should be able to incorporate these principles into a research proposal.
- In the early ATP, students should be able to describe the steps needed to prepare a proposal for review by the Institutional Review Board (IRB) for the responsible conduct of research in human subjects (or Institutional Animal Care and Use Committee for animal research).
- By the late ATP, the student is expected to proactively apply the principles of responsible conduct of research by taking appropriate steps to preserve the integrity of the research process and protect privacy and rights of subjects and be able to work with their faculty mentor to ensure the ethical integrity of the research progress.

Progress towards these objectives is assessed at regular intervals throughout the pre-clerkship phase and ATP. Mastery of these objectives is assessed via the submission of the MD Thesis during the fourth year of medical school. The only exception to the MD thesis requirement pertains to students who have completed a PhD in the biomedical sciences prior to YSM matriculation or who are concurrently conducting PhD research through their enrollment in YSM's MD/PhD degree. Students who have completed a PhD prior to YSM matriculation should contact OSR to determine if their dissertation is sufficiently health oriented to fulfill the thesis requirement. Students in the MD/PhD program should work with the MD/PhD program to ensure that the date of their dissertation defense is submitted to OSR.

Project Requirements

YSM's research-related educational objectives are achieved through hands-on conduct of investigative projects conducted under the supervision of a YSM faculty mentor. A wide choice of research topics is available. Students may choose laboratory projects in the basic or translational sciences, or clinical projects in an array of disciplines including, but not limited to health outcomes; health services; health equity studies; community based participatory research; qualitative; humanities and medicine (including ethics and the history of medicine); sociology; economics; or education research.

Four basic requirements apply to all research projects: (1) the subject chosen must address an important question in medicine; (2) the work must pursue a clear, concise aim that can be addressed by new knowledge generated by the student's research; (3) data must be collected and analyzed with the most rigorous methods suited to the research question; (4) the research sponsor be a full-time YSM faculty member.

Elements of the Yale Curriculum Favorable for Student Research Yale SCHOOL OF MEDICINE Office of Student Research Yale's commitment to research as a central component of medical education is reflected by the following attributes.

- 1) The long tradition of medical student research at Yale with a MD thesis requirement is unique.
- 2) There is an established tradition for Yale faculty to welcome students as colleagues in a community of scientists.
- 3) There is a high student/faculty ratio
- 4) The deep pool of role models and mentors fosters intellectual and professional development of future clinicians and physician scientists in all domains.
- 5) The vast majority of faculty members in both basic science and clinical departments are located within a 6-block medical center campus contiguous with Yale-New Haven Hospital, facilitating students' access to mentors, laboratories, and research groups.
- 6) YSM recruits an outstanding body of students who at the time of matriculation are aware of the expectations for rigorous, reproducible, and creative scholarly work.

For close to two centuries, this system has inspired the careers of numerous Yale Medical Students and continues to do so to this day.

Formal Didactics

Students are formally prepared for their research through the longitudinal "Scientific Inquiry" Course during the first year of the pre-clerkship curriculum. Scientific Inquiry (SI) provides students with practical tools required to perform rigorous, ethical, and responsible research in all domains, and supports the mentor selection process through lectures, workshops, and peer mentoring. The SI syllabus and course objectives can be found in BlueDogs. SI combines formal didactics with small working groups (<10 students) led by successful, early career physician-scientists with inverted classroom approaches, nearpeer and peer-to-peer feedback, and independent work to support initial progress towards research related educational objectives through the development of mentored research projects. The central focus of the small working groups is the process of mentor selection and the development of a scientifically significant, innovative, and feasible research project. To receive course credit, all MD students (even those with a PhD exempt from the thesis requirement) must submit a formal research proposal that is assessed by their mentor according to YSM's research-related educational objectives. Embedded within SI are "Responsible Conduct of Research" (RCR) modules. This training series fulfills institutional and federal requirements for education in the ethical and practical aspects of appropriate research conduct. Attendance at all RCR training sessions is required for compliance with federal research regulations and is mandatory for students seeking research funding from OSR.

Time Available for Research

Students have many opportunities for research participation throughout their medical school career. Most students begin research work during the summer following their first year. For example, during the summer of 2023, >96% of eligible first year medical students conducted mentored research on a wide variety of projects. Students working under the supervision of a Yale faculty mentor are eligible to receive financial support at the level of an NIH pre-doctoral stipend for this time period (see below). Many students continue their research work part-time in the afternoons, evening, and weekends during the second year of medical school. Additional blocks of 1-3 months are available during the ATP (last half of the third year and into the fourth year). Students interested in having additional time for research may partake of YSM's unique tuition-free fifth year opportunity (see below).

As a reminder, the rigorous generation and collection of reproducible data can take many months. Yale SCHOOL OF MEDICINE Office of Student Research 8/39 Additional time is then required for analysis and the subsequent preparation, submission, revision, and ultimate publication of the thesis and any manuscripts resulting from the project. Therefore, students are encouraged to work with their mentors to develop a realistic timeline for project completion. Please contact Deans Chaudhry or Herzog with questions.

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A close working relationship between the student and faculty research mentor is a major goal of this program and is strongly encouraged. When laboratory research is performed, it is the responsibility of the faculty advisor to provide all necessary space, equipment, and supplies, including costs of publication of scientific articles. For non-laboratory investigation, the same commitment to guidance and support is expected, including but not limited to data access, statistical analysis packages, statistical and methodological support, abstract and publication costs, etc. Weekly meetings between student and advisor are encouraged during the course of the research. It is important to note that, where practicable, the research must be specifically performed by the student with the advice of the faculty mentor. Medical students may not solely fulfill research duties expected of a research coordinator or laboratory technician absent of independent scholarly contributions. They may also not work jointly on a research project. If a faculty member chooses to mentor several students concurrently, each student should receive equal support and attention. Specific components of the research blocks are offered in the Scientific Inquiry Course and provided in detail below.

Opportunities for medical student research participation

Students many participate in any or all of the following opportunities for mentored research throughout their medical school training. These opportunities are: 1) the START program, 2) summer research after first year, 3) research electives in the Advanced Training Period, 4) "fifth year" short-term and year-long research.

<u>1) START</u>: The START program ("Summer to Advance Research Training at Yale") offers accepted firstyear MD students the opportunity to matriculate 8 weeks early to engage in a laboratory or clinical research rotation with a specific project in selected research environments. This pre-clerkship program was developed in recognition of the fact that not all students have had the opportunity to participate in structured research prior to medical school entry and may benefit from early, intensive exposure. A core component of the START program is a lecture series on research topics from faculty committed to student mentorship. This didactic series complements the students' "hands on" research conducted throughout the program. The culmination of the START program is a full-day symposium which provides students the opportunity to present their research to their peers and START faculty. Many students remain with their START mentor throughout medical school and use the project as the basis for their thesis.

2) Summer Research: The next opportunity for participation in research occurs in the summer between the first and second years of medical school, during which students in the pre-clerkship period conduct 8-11 weeks of mentored research under the supervision of a Yale faculty member. This summer research project is developed by the student-mentor dyads in the context of the first-year Scientific Inquiry course. Participating students receive instruction in specific research methods and analytical skills from their mentor and research group members. Progress is supported and assessed by OSR in the "Applied Principles of Research" seminar series that provides a venue for students to present their work and to receive feedback on both the methodologic rigor of their research project and their ability to both present

and answer questions about their work. Each student's research preparation and progress toward YSM educational objectives are assessed by the mentor at the end of the summer, and by OSR through the review of a self-assessment and progress report that comprise the formal summer research "deliverable." These assessments can be found in the Medtrics dashboard platform. For approximately 50% of students, summer research will contribute to the MD thesis and is expanded upon during the ATP and/or fifth year. Over the last 15 years, \geq 95% of first year medical students have participated in YSM's summer research program.

3) <u>Research Electives in the Advanced Training Period</u>: Research is typically suspended during the clinical clerkships, after which students may engage in full-time research electives for up to 16 months during the Advanced Training Period. For the 2023 graduating class, the mean ATP research duration was 6 months. Having completed clinical clerkships, students typically have decided upon their chosen specialty and the vast majority of ATP research serves as the foundation for the MD thesis. As noted above, approximately 50% of students continue to work on the MS1 summer research project while an approximately equal proportion initiate a new project informed by interests and mentors encountered during clinical rotations. Students are assessed for research preparation, performance, and progress towards YSM's research related educational objectives at the end of each elective block through evaluation by their mentors and the submission of progress reports in Medtrics. Research conducted during the ATP typically forms the basis of the thesis.

<u>4) Fifth Year Research:</u> Research opportunities during the ATP can be extended by up to one year during YSM's unique, tuition free "fifth year" of medical school (which chronologically precedes the year of graduation, or "fourth year"). Mentored research options during this extra year include either committing the entire year to full-time research as "one-year fellows" (approximately 25% of fifth year students), or pursuing "flexible" short-term research in consecutive blocks of 4-12 weeks (approximately 75% of fifth year students). Assessment of progress towards mastery of educational objectives occurs at regular intervals throughout this period via the Medtrics platform. Over the last few years, approximately 65% of eligible students have partaken of these opportunities. One-year fellows are typically research-oriented medical students who envision scientific investigation as the central focus of their future careers. As such, their research training is supplemented with opportunities for professional development and cohort building in the form of seminar series and other research-related events. Regardless of the type of fifth year pursued, research conducted during this period typically forms the basis of the thesis.

General principles of medical student research

Most students begin their formal research training during the summer between the first and second years. This period is viewed as an immersive experience in which students are fully engaged in mentored investigation, for which students are prepared through a combination of didactics, Responsible Conduct of Research training, Scientific Inquiry workshops, 1:1 meetings, and OSR-coordinated peer interactions. Similar to the exploratory rotations conducted by PhD students, summer research serves as an opportunity to develop a mentored project and is not necessarily expected to become the thesis project. Additionally, due to its limited scope and duration, students should not expect to generate sufficient data for a publication during this short period. Students whose summer research has led to a publication typically continue with their mentor throughout subsequent years. Another point to consider is that for some summer research topics, time constraints may necessitate the student working on a project designed solely by the faculty mentor. In this circumstance, the student should identify a portion of the work which they can lead independently.

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Suggested timeline. It is suggested that students start thinking about their summer research during the fall of their first year for several reasons. First, the selection of a topic and mentor is a lengthy process. Second, developing a research question and establishing a protocol requires adequate time and effort. Third, some forms of research -- particularly human-oriented work -- involve specific regulatory or data needs that can take several months to address. Last, students wishing to compete for external funding may have deadlines preceding the OSR submission deadline by several months. However, while YSM students are encouraged to start thinking about research shortly after arriving at Yale, they are by no means expected to participate in research until the summer after the MS1 year. In consideration of these factors, the suggested timeline for the vast number of medical students conducting research in New Haven* in the summer following the first year is as follows.

- 1) **October May:** Attend all Scientific Inquiry and Responsible Conduct of Research course sessions to gain an introduction to the YSM research requirement and support for developing the summer research project and (in the case of Responsible Conduct of Research) to be eligible for funding.
- 2) November-January: Identify potential faculty mentors and meet to discuss possible projects.
- 3) **January-April:** Decide on a faculty mentor and project, start work on research proposal. Incorporate feedback from faculty mentor and SI small group into proposal.
- 4) **Mid-April:** Receive Thesis Chair approval for research proposal. Submit approved application to OSR for review/approval for credit and funding. Applications from students who have not completed all Responsible Conduct of Research sessions will not be approved for funding.
- 5) June August: Receive funding, conduct research, attend summer research didactics
- 6) August-September: Conclude project and complete self-assessment/progress report in Medtrics

*Due to logistical aspects of global health research, students planning to conduct global health research should select a mentor and develop the proposal much sooner (in November and December). Students performing global health research should also explore the Downs Fellowship Program (see <u>Global Health</u>) are required to complete Yale's required travel preparation (see below). Finally, students wishing to apply for external funding should familiarize themselves with sponsor deadlines and plan their research accordingly. As with all YSM students, completion of the Responsible Conduct of Research sessions is required for students seeking OSR funding for Global Health work. If there are any questions about any part of this timeline, please contact OSR.

Advanced Training Period and Thesis Research. As stated above, many students choose to use the summer research project as the basis for subsequent research and, ultimately, the thesis. An equal proportion choose to pursue a different field of thesis study under the supervision of a different faculty mentor. Either of these tracks is acceptable. Students wishing to embark upon an alternate project for their thesis may identify a mentor using the methods described below. Additionally, students are often inspired by a clinical problem encountered during rotations. In this case, supervising attending physicians may be suitable mentors as long as they are full time YSM faculty experienced in research.

Thesis research typically begins in earnest during the Advanced Training Period (ATP). Aside from elective start and end dates, short term funding deadlines, and the thesis submission timeline, there is no uniform scheduling requirement for ATP research. Students are expected to use their skills as adult **Yale SCHOOL OF MEDICINE Office of Student Research** 11/39

learners to develop a self-directed timeline appropriate for their projects and should remember that data collection can take many months. Additional time is then required for data analysis, and the preparation, submission, revision, and ultimately publication of the thesis and any manuscripts resulting from the project. Therefore, students are encouraged to work with their mentors and YSM advisors to develop a realistic timeline for researching and writing the thesis. All students participating in research during the ATP are required to register their research blocks and mentor into MedHub. Questions and advice regarding research during the ATP can be directed to OSR. Questions and advice regarding MedHub logistics should be directed to Student Affairs. In the event that research conducted during the ATP serves as the basis for the MD Thesis, students graduating in 2024 should adhere to the procedures and timelines presented in the section Thesis Requirement, Preparation, and Approval Process.

IDENTIFYING A MENTOR AND PROJECT

YSM's <u>robust system for finding a research topic and mentor</u> ensures that students receive personalized support tailored to their unique needs and interests. It is recommended that students perform a preliminary mentor search and select between four to six individuals with whom to make preliminary contact. Students should then <u>reach out by email</u> requesting appointments to learn about current research and discuss possible research projects. Students should attend research group meetings and meet with research team members in the absence of the mentor to gain insight into the group's culture, climate, and operations. Finally, the student should meet again with the chosen faculty member to develop a proposal for the project. The faculty member should make every effort to orient the student to a practical research question that can be answered within the available time and, to the extent possible, should encourage the student to contribute to the project by formulating an independent and original question.

Don't forget – faculty spend considerable time meeting with prospective students about research opportunities. While everyone understands that students are meeting with multiple mentors, it is courteous to "close the loop" and let faculty know if you have decided to conduct your research project with the mentorship of another faculty member. They will understand but appreciate hearing the outcome from you!

<u>Directories</u>: OSR maintains a listing of > 450 recent and ongoing research projects conducted with Yale faculty mentors conducted since 2018. This resource is complemented by the <u>Directory of Faculty</u> <u>Research Interests</u>, a search engine that allows students to search for prospective mentors via topic, Medical Subject Headings (MeSH), department, or faculty name.

<u>Scientific Inquiry</u>: This <u>longitudinal course</u> extends throughout the entire first year curriculum. It combines formal didactics with small working groups (<10 students) led by successful, early career physician-scientists and employs inverted classroom, near-peer and peer-to-peer feedback, and independent self-study to support the development and preparation of mentored research projects. The working groups' major goals include the process of mentor identification and the development of a scientifically significant, innovative, and feasible research project.

<u>YSM Advisors</u>: All YSM medical students are assigned a faculty advisor who meet regularly with their assigned students and are an important source of information about potential faculty mentors and projects. The Associate Deans of Student Research meet with the advisors on a quarterly basis to discuss issues related to the student research program and forecast upcoming deadlines for research proposals and the MD thesis requirement.

<u>Weekly Office Hours with Associate Deans of Student Research:</u> Deans Chaudhry and Herzog hold separate weekly office hours for 1:1 guidance in identifying a research project and mentor. This venue provides personalized, private counsel for students engaged in a mentor search.

<u>YSM Departmental Thesis Chairs:</u> Each department within the Yale School of Medicine assigns a faculty member to serve as "Departmental Thesis Chair." In addition to stewarding review of the required MD thesis, these Chairs serve as an additional mentor identification resource. Their close connections with faculty in their department enables them to provide students with information about potential mentors working in students' area of interest.

<u>Student Interest Groups</u>: There are over 60 student interest groups at Yale, many of which focus on medical and scientific specialties. These groups serve as venues for dissemination of research opportunities, as well as formal and informal networking with faculty.

<u>Near-Peer Mentoring</u>: Recognizing the importance of near-peer perspectives by upper-year students, Yale Medical Education provides support for Research Representatives of the Medical Student Research Council to hold research meetings throughout the year. The Research Representatives have also compiled an <u>online manual of near-peer advice</u> and best practices for student research, including mentor identification.

DEVELOPING A MENTORED RESEARCH PROJECT

OSR adheres to the NIH definitions for research and research subcategories, wherein "research" is defined as, "a systematic study directed toward fuller scientific knowledge or understanding of the subject studied." Most YSM students conduct research that falls into one of the following categories, presented below alphabetically. No matter what their topic area, most students conducting research as part of the YSM thesis requirement present their work at national conferences and publish at least one paper, often as first author, in peer reviewed medical journal during their time at Yale. Students who do not see their area of interest listed should contact OSR for input.

Basic-Laboratory Research

The NIH defines basic research consistent with the definition of basic research published <u>here in federal</u> <u>code</u> as, "systematic study directed toward greater knowledge or understanding of the fundamental aspects of phenomena and of observable facts without specific applications towards processes or products in mind." Because medical student research questions are designed to address a specific medical question, these studies may also be termed "laboratory based," or "experimental," to reflect their conduct in a scientific laboratory and the performance of experiments that generate quantitative data from biological substances. Hypothesis-driven studies aimed at investigating biological processes conducted at the laboratory bench fall under the federal definition of STEM (Science, Technology, Engineering, Math) based, life sciences research. These projects may involve methods including but not limited to cell culture, animal modeling, human biospecimens, and secondary analysis of large genomic datasets. Due to the significant costs and practical needs associated with laboratory research, students pursuing these studies should select mentors with expertise and resources (funding, space, personnel) sufficient to support the proposed work. Pre-clerkship projects should have appropriate scope and aims to be conducted within the proposed period. Laboratory based projects pursued during the ATP are likely to entail more detailed and comprehensive investigations of biological processes.

Clinical Research

The NIH defines clinical research as "a component of medical and health research intended to produce knowledge valuable for understanding human disease, preventing and treating illness, and promoting health." Clinical Research embraces a continuum of studies involving interactions with patients, diagnostic clinical materials or data, or populations in any of the following categories: (1) disease mechanisms (etiopathogenesis); (2) bi-directional integrative (translational) research; (3) clinical knowledge, detection, diagnosis and natural history of disease; (4) therapeutic interventions including development and clinical trials of drugs, biologics, devices, and instruments; (5) prevention (primary and secondary) and health promotion; (6) behavioral research; (7) health services research, including outcomes, and cost-effectiveness; (8) epidemiology; and (9) community-based and managed care-based trials. This comprehensive definition can be found in this reference. Health equity research typically falls under the larger heading of clinical research.

Clinical research can be "quantitative," which uses numerical data to test hypotheses; "qualitative," which uses non-numeric data to generate hypotheses and a deeper understanding of complex phenomena; or "mixed-methods" which combines qualitative and quantitative approaches, typically in a triangulated fashion, so that insights from the qualitative components inform the quantitative design. As with laboratory-based work, students interested in clinical research should identify mentors with expertise and resources such as funding, personnel, infrastructure, and access to patient cohorts and data to allow the proposed work. To maximize feasibility, pre-clerkship summer projects should be designed with the goal of being completed within a 2–3-month research block whereas clinical projects conducted during the ATP can be more far reaching and complex.

Global Health

Global health research has been defined as "an area of study, research, and practice that places a priority on improving health and achieving equity in health for all people worldwide" according to <u>evolving</u> definitions. The Yale Institute for Global Health formed by Yale's Schools of Medicine, Nursing, and Public Health has a long tradition of providing students opportunities for mentored research in international settings. Many YSM medical students work with Yale mentors who participate in the <u>Global Health Equity Scholars program</u>. Practically, while global health is a form of clinical research, it presents a set of unique challenges that may not be immediately evident, including butnot limited to: 1) language and cultural competency, 2) regulatory approval, 3) dual mentoring (Yale and local), 4) resource limitations, 5) social/infrastructure constraints, 6) personal safety, 7) feasibility, and 8) travel/visa restrictions.

YIGH has developed a Global Health Ethics Program (GHEP), that provides trainings in clinical ethics (led by Professor Tracy Rabin of YSM) and in research ethics (led by Professor Kaveh Khoshnood of YSPH) to Yale health professional students. More information can be found <u>here</u>. We strongly urge medical students pursuing global health research projects to contact Professor Kaveh Khoshnood (<u>Kaveh.Khoshnood@yale.edu</u>) to learn about the pre-departure global health ethics training program before they embark on their research projects.

Students pursuing research in international settings should explore the Downs Fellowship program, which not only provides partial funding for research but offers invaluable logistical and safety training for students. More information about the Downs Fellowship can be found <u>here.</u> Students may also contact the Downs Program leadership, Dr. Leonard Munstermann, PhD, (leonard.munstermann@yale.edu) and Dr. Sunil Parikh, MD, (sunil.parikh@yale.edu) or the Assistant

Director, Ms. Anjuli Bodyk, (<u>anjuli.bodyk@yale.edu</u>) at the Yale School of Public Health with questions. The global health research conducted by YSM medical students is often the basis for the thesis and related publications.

Yale medical students participating in global health research for which they are receiving curricular credit MUST:

- 1. Review <u>Yale and the World</u> and the <u>International SOS system</u>.
- 2. Download and print the <u>ISOS Membership Card</u> containing information on what to do in an emergency.
- 3. <u>Register their travel</u>. Requires NetID and password to access.
- 4. Contact <u>CIBT</u> for assistance and support with passports and visas.
- 5. Attend Pre-Departure Orientation and Ethics Workshop (please review information on taking photos). Please contact OSR for dates and registration information.
- 6. Complete Travel Health Requirements (information found <u>here</u>)
- 7. Meet with their faculty mentor regarding country specific information on conducting research

Humanities in Medicine

Research in humanities, ethics, history, and related fields allows students to study medicine's place in society. Dual mentorship often is particularly appropriate for these topics and enables students to draw upon the rich faculty base available elsewhere in the University. The History of Medicine Department is an outstanding resource for these types of studies. In addition, <u>The Program for Humanities in Medicine</u> can help students select prospective medical school mentors and identify co-mentors from across the University whose primary faculty appointments are outside of YSM. Each year a small number of YSM students pursue this type of work as the basis for their summer project, ATP research, one year fellowship, and/or thesis and publications. Medical students interested in pursuing a humanities-based research project should reach out to OSR.

Medical Education

The YSM <u>Center for Medical Education</u> was founded with the mission of supporting and enhancing the work of YSM educators in medical education research and scholarship. This resource is poised to guide medical students to experts in these fields when they are seeking a thesis mentor. Center faculty understand that medical education research is an important and discrete area of study with numerous and varied topics to investigate and they have the expertise in these unique methodologies, designs, and statistical formulations. Over the years, hundreds of YSM faculty, residents and students have benefited from educator development programs such as the MHS in Medical Education Pathway Degree Program and the Medical Education Fellowship.

At this link can be found a document published by the <u>AAMC</u>, <u>Research in Medical Education – A Primer</u> <u>for Medical Students</u>. This article outlines some of the opportunities in this broad and exciting field of research. More information can be obtained by contacting <u>centermeded@yale.edu</u>.

APPROACH TO DEVELOPING A PROJECT

Project Requirements

When the area of investigation has been mutually agreed on by the student and their faculty preceptor, project development begins. All projects must adhere to the foundations of the scientific method, which

involves developing a research question or hypothesis, participating in the design and conduct of rigorous and ethical research, collecting and interpreting data, and disseminating results to communities of interest. All projects must be conducted under the mentorship of a faculty member with a full-time appointment at Yale School of Medicine. Students wishing to conduct research with a non-YSM mentor should contact OSR.

Project Objectives

At the minimum, projects should address four basic objectives.

- 1) The student is expected to explore the literature to identify a clear knowledge gap that can be filled by the proposed research
- 2) The student should formulate an investigative protocol and experimental plan. This step provides a unique opportunity for tutorial instruction in experimental design.
- 3) All research plans should adhere to high standards of rigor and ethics. In addition, as relevant, projects should adhere to NIH research requirements related to rigor and reproducibility and the appropriate research conduct
- 4) All projects should contain a clear vision for their potential dissemination to and impact on communities of interest.

These components are formally addressed in SI course and RCR training curricula. Faculty members who assume responsibility as preceptors should provide the amount of guidance that is necessary in design of the investigation. General principles that adhere to the scientific method and apply to many types of projects are provided below.

Principles that apply to many types of projects

- 1) Perform a literature search The goal of the literature search is to understand the current state of a given field and to identify key knowledge gaps that the project may address. The Cushing Whitney Medical Library offers students access to all major databases, with the most commonly used medical database being Medline (also called <u>"PubMed"</u>). PubMed is housed within the National Library of Medicine and uses MeSH headings. OSR recommends that students consult with their assigned Medical Librarian throughout this process, with the caveat that librarians are available for instruction and advice but that the student is responsible for conducting their own search.
- 2) Specify a Clear Knowledge Gap Excellent research begins with an excellent research question developed through literature review and mentor discussions. Ideally, the research question and specific aims should be original and of sufficient significance that any answer is important and will advance the field. Research projects may collect new data. or analyze existing data or publications (e.g., meta-analysis). Student/mentor dyads who are unsure as to how their project can ask a question and generate outcome measures should contact OSR. Outlined below is a sequence for developing a quantitative research project. While these steps do not apply to some forms of qualitative research and projects in the medical humanities, they are useful in illustrating a rigorous approach to research proposal development. Certainly, some steps, such as starting with an impactful question, developing a clear study protocol, and establishing plans for data collection and management apply to nearly all types of research.
- 3) Frame a research question In the case of hypothesis-driven research, convert the question to

a hypothesis by asserting a position. This will lead directly to a consideration of measures, both of exposure and outcome. Because qualitative research is hypothesis generating, this step does not apply for this type of work.

- 4) Generate measures of exposure and outcome This step is facilitated by an additional review of the pertinent literature. How have other researchers defined/measured the exposure and/or outcome? The effort to generate meaningful measures will require a return to the question for refinement, and narrowing (i.e., expressing the question in terms of the specific exposure of interest, and the specific anticipated outcome).
- 5) Construct an experimental approach and research protocol How can the specific aim(s) be accomplished? The first requirement is that a comparison be made. Here, too, a search of the literature for methods will be helpful. Choosing the right control group can be both and subtle. Once the comparison group is selected, the magnitude of expected difference should be estimated as a basis for determining sample size (power calculation).
- 6) Revise and refine In light of the design deemed most appropriate, revise measures of exposure and outcome as required. For example, in a prospective study, researchers can choose how to measure factors of interest, whereas in a retrospective study the team must rely on measures obtained in the past, or by participant recall.
- 7) Develop an analytic plan When the results of an investigation lend themselves to quantitative analysis, the student should develop a prospective and robust plan for statistical comparison. Personal involvement in the conduct of research will aid the iterative process and support the pedagogical goals of the research experience. Students should be adequately equipped for basic statistical work through the Biostatistics Coursework offered as part of Populations and Methods. Advanced work may require the aid of a biostatistician for assistance in statistical methodology performed with mentor support. Ideally this process will augment the preclerkship coursework and will enable the student to learn the value and limitations of statistical analysis as an aid to interpreting the results of an investigation. Drs. Chaudhry, Herzog, and Hajduk are available to answer questions and provide advice if needed. Students may also take advantage of Yale's Prevention Research Center (PRC), located off-campus in Derby. This facility is a resource for students needing assistance with data management and/or statistical analysis, survey development and validation, as well as refinement of clinical study methodology. The PRC data management staff will work with students to perform statistical analysis using a variety of software packages. Referrals can be provided as needed to additional resources available through the computer labs at the Yale Schools of Public Health and Management. The contact is Dr. Valentine Njike, Assistant Director, Research and Evaluation, at valentine.njike@yalegriffinprc.org.
- 8) Determine feasibility Once measures are established, next steps involve determination of the appropriate sample size, methods of analysis, and plans for replication. A plan for the generation, collection, and management of data should also be developed. Now is the time to assess feasibility to ensure that the outcome events be observed and suitably analyzed using the proposed methods in the available time.
- 9) Plan for Dissemination to Stakeholders An additional consideration is how the results will be disseminated to communities of interest including patients. Dissemination to other scientists usually occurs through presentation scientific at meetings and publication in peer reviewed medical journals. Dissemination to patients and community groups may be achieved through meeting with community leaders, support groups, or providing access to a summary of findings. Students are recommended to consider how their work will impact these groups.

Some forms of research, such as medical humanities or education, will differ from the path outlined above. Students with interest in these types of projects should contact OSR for input.

Additional Considerations

In an effort to ensure that student research projects are conducted in accordance with regulatory and ethical standards, with the maximum impact for patients and other stakeholders, OSR provides guidance in the following areas.

- 1) Ethical Conduct Ethical conduct is central component that should be incorporated into all studies. Instruction in research ethics will be provided in the Responsible Conduct of Research training series throughout the 2023-2024 academic year.
- 2) Regulatory Requirements Most forms of research are subject to university regulatory oversight. Laboratory based projects require completion of relevant Environmental Health and Safety (EHS) training. Animal research must be approved by the Institutional Animal Care and Use Committee (IACUC) training. Clinical research involving human subjects must be approved by the Human Research Protection Program (HRPP, formally known as Human Investigation Committee) at YSM. The Scientific Inquiry course and RCR training will review these requirements, all of which are available on the <u>Yale TMS Training and Certification</u> website. It is the mentor's responsibility to ensure that students are approved to work on all relevant protocols and to enforce compliance with institutional guidelines, including secure data management and HIPAA. Discussion of regulatory requirements will also be provided in RCR throughout AY 2023-2024. All students receiving OSR funding are required to provide their relevant protocol numbers within one month of funding.
- 3) Data access and management Most research projects are expected to generate some form of data. For projects proposing use of an existing dataset or resource, students should confirm the existence and availability of the dataset. Students and their mentors are responsible for identifying the appropriate method(s) for data storage and transfer. OSR highly recommends students use Yale-approved managed workstations and data encryption methods and/or cloud-based storage systems. As a reminder, google drive is never appropriate for storage of confidential, sensitive, or HIPAA-protected data. Furthermore, Yale ITS prohibits the storage of protected health information (PHI) on personal laptops. For more information, see https://cybersecurity.yale.edu/protectyourdata and https://cybersecurity.yale.edu/data. As a reminder, the faculty mentor is ultimately responsible for ensuring that all data are securely managed in compliance with relevant local and federal regulations. Data Acquisition and Management will be addressed in RCR.
- 4) Joint Projects Are Not Acceptable A project conducted jointly by two or more students is not acceptable. This does not mean that they may not work on related problems, but each student should have the experience of carrying out an investigation from beginning to end on their own initiative.
- 5) Rigor and Reproducibility YSM's research curriculum aims to educate students in the conduct of rigorous, reproducible, and ethical research. Rigor is the strict application of methodologies in order to achieve unbiased, well controlled experiments that are analyzed, interpreted, and reported appropriately. Rigor is the cornerstone of reproducibility, which denotes the property of results being repeated and confirmed by multiple scientists working independently. These facets are considerations in all investigative efforts. Hence, OSR requires that all research projects adhere NIH standards which can be found here: to https://grants.nih.gov/policy/reproducibility/index.htm. Formal instruction in these topics

is provided in the SI course and are thematically addressed in RCR. Students who are unsure as to how the concepts of rigor and reproducibility apply to their particular project are encouraged to contact OSR.

- 6) Sex and Gender The 1993 NIH Revitalization Act (PL 103-43) included a Clinical Equity Provision requiring that women be considered as participants in NIH-supported clinical research. Implementation guidelines were placed in the Federal Register in 1994 and the most recent policy can be found here: <u>https://grants.nih.gov/policy/inclusion/women-andminorities/guidelines.htm</u>. In 2001, current definitions of sex and gender were developed, with sex as a biological classification and gender as self-representation or sociocultural identification. The NIH provides this <u>guidance</u> and <u>resource</u> for investigators. It is recognized that societal definitions of sex and gender are continuing to evolve. Discussion of appropriate handling of sex and gender in research will be discussed in the RCR series during the 2023-2024 academic year.
- 7) Race and ethnicity The above provision also stipulates that racial and ethnic minorities be considered as participants in NIH-sponsored studies. Considering this dictum, all clinical research that includes race as an analytic variable should consider the following aspects which will be addressed in the Scientific Inquiry Course and RCR training. First, there should be clear explanation of whether race is being included to reflect political categorization, cumulative physiological impact of experiences of interpersonal or structural racism, or as a proxy for geographic ancestry. Second, when race is included in a model, clearly explain the hypothesis or perceived confounding relationship and how a finding of an association or mitigation of the outcome would be interpreted. It is also important to consider the role that racism may have in the findings. Finally, students should consider whether there is any potential for racial bias in participation in the research and its perceived benefits to communities of interest. Students with uncertainty regarding the appropriate consideration of race in their study should contact OSR. Discussion of appropriate handling of race in research will be discussed in the RCR training series during the 2023-2024 academic year.
- 8) Authentication of key biological/chemical resources Projects conducted in the laboratory employ the use of key biological and/or chemical resources. According to current <u>NIH policy</u>, these entities include but are not limited to: "cell lines, specialty chemicals, antibodies and other biologics...[these resources] 1) may differ from laboratory to laboratory over time; 2) may have qualities and/or qualifications that could influence the research data; and 3) are integral to the proposed research." Consistent with current NIH guidelines, projects must include information regarding the authentication of these entities. Resource authentication will be discussed in RCR.
- 9) Additional Considerations We have attempted to highlight the most relevant considerations in research design and conduct. Students needing help with an issue that is not addressed above should contact OSR.

Additional Scholarly Resources

While OSR provides substantial support for YSM medical students, it is recognized that certain types of projects may require additional expertise. Listed below are additional scholarly resources that students may find helpful.

<u>Biostatistical and methodologic support:</u> The <u>Yale Center for Analytic Sciences</u> was developed in partnership with the Yale Center for Clinical Investigation and the Yale School of Public Health. It

provides all members of the YSM community, including medical students, with free consultations on study design, conduct, and analytic approach. The Office of Student Research has also retained a faculty member (Dr. Valentine Njike) at the Yale Prevention Research Center to provide focused individualized support with statistical analyses, survey development, and refinement of study methodology.

<u>HRPP Support</u>: The RCR series provides an introduction to regulatory issues. This training is augmented by the Yale HRPP's provision of 1:1 guidance to all investigators seeking research approval, including determination of exemption status for minimal risk and quality improvement studies. The HRPP also maintains a <u>web page</u> specifically for student research and participates in medical student oriented pop-up content sessions developed by OSR for medical students.

<u>EPIC access</u>: Research-related access to the electronic medical record is granted by Yale New Haven Hospital's Health Information Management (HIM) Office. Access for students engaged in research is granted after a mentor completes and submits this <u>form</u> which requires a copy of the IRB approval for the protocol on which the student is authorized to gain medical record access. The YNHH HIM can be contacted at EpicCare.eHIM@ynhh.org

<u>Library</u>: The Yale Cushing Medical Library employs 19 medical librarians to support research, including through 1:1 consultation to guide and/or conduct background literature searches. They also teach classes on research data management, reference management software, databases for biomedical literature searches, and systematic review methodology. Medical librarians participate in OSR's research program by serving as large group didactic instructors, providing asynchronous instruction for students, participating in pop-up content sessions, and offering and "Night Owl" thesis sessions for students conducting after hours academic work.

FUNDING FOR STUDENT RESEARCH

OSR provides funding for student research in the form of stipends, research costs, and conference travel reimbursement.

Research Stipends

All medical students who commit to at least 8 contiguous weeks of full-time research during the summer after the first year of medical school, or at least 4 contiguous weeks during the ATP and fifth year, are eligible to receive a research stipend. All students are paid the same dollar amount, regardless of funding source. Students who receive funding must have completed the Responsible Conduct of Research training during their first year and have renewed this requirement every four years. Stipends are provided at the NIH predoctoral level, which may be adjusted by the federal government at various times throughout the year. This amount is currently set at \$566 per week, or \$6786 for 12 weeks. "Full time research" is defined as 40 hours per weeks conducted during daytime, weekday work hours. Because research stipends are provided to support full time research training, students may not be enrolled in electives or subinternships – no matter how small the hourly time commitment -- during their period of stipend support. By accepting a stipend, the student agrees to the terms set forth in their award letter. For graduating students engaged in residency applications, interviews, and thesis writing, financial support is not provided after October 31 of their fourth year. All stipends are paid weekly for work done during the prior week and there may be a lag of up to two weeks before the first payment is administered. Due to Yale's payroll logistics, the first stipend payment may be paid as a paper check regardless of whether the student has set up direct deposit. Because the first stipend payment is mailed, students are encouraged to 20/39 Yale SCHOOL OF MEDICINE Office of Student Research

update their mailing address in the Yale Workday financial management system to avoid delays in receipt. Questions regarding stipend logistics should be directed to OSR. Questions regarding the impact of stipends on financial aid should be directed to the financial aid office.

Applying for Research Stipends

Student seeking OSR stipend support should prepare a brief (4 page) research proposal and complete the complete appropriate application form (found here). The signed form and proposal documents should be transmitted to the thesis chair of the department in which the mentor holds their primary faculty appointment. The thesis chair submission deadline precedes the OSR deadline by two weeks (see below). The thesis chair will review the application, provide any needed feedback, and sign the application. Students should then submit the completed application to OSR. Students are encouraged to do their utmost to meet these deadlines in order to develop the habit of self-accountability that is required of physicians. However, it is recognized that circumstances may arise for the student or mentor that warrant an extension. In this case, students should contact their thesis chair with the request. Please note that applications from students who have not completed Responsible Conduct of Research and obtained an <u>ORCID iD</u> to uniquely identify their scholarly products cannot be considered for funding.

The Office of Student Research provides three types of stipend support for student investigators.

1) Summer Research Summer research stipends are awarded specifically to students between the first and second year. Students are required to conduct 8-11 contiguous weeks of full time, mentored research. The amount for 2024 is currently being updated and will be released after the NIH updates federal stipend levels in early 2024. Students wishing to receive support for summer research must complete RCR training and obtain an <u>ORCID iD</u> to uniquely identify their scholarly products.

2) Short-term Research Short-term stipends are awarded for specific blocks of 1-3 months during the academic year when full-time research is performed (ATP or fifth year). To ensure adequate research time and comply with funding sources, research durations of less than one month (4 weeks) are not eligible for OSR stipend support. Also, students in their fourth year are <u>not</u> eligible for short-term research stipends while interviewing for residency, writing their thesis, and participating in the Capstone project. The final funding cycle for students in their fourth year is during the months of September through October of the student's expected year of graduation. Stipends are funded at a level of \$2,264 per 4-week block and are supported by a variety of Yale-administered funding sources (NIH, private donors, and University funds). Because the NIH typically updates stipend levels early in the year, this amount may be subject to change. Students wishing to receive short term research funding from a Yale-administered fund must have completed RCR training and obtained an <u>ORCID iD</u> to uniquely identify their scholarly products.

3) One-year Medical Student Research Fellowships Students choosing to pursue a fully funded fifth year of research are eligible for stipend support provided by OSR. Depending on the source, the stipend value is \$26,352 - \$37,000 (subject to change in AY24). These stipends derive from numerous sources (NIH, private donors, and University funds). Students considering a fully funded one year fellowship should contact OSR to discuss the process and obtain applications. Additional information can be found on OSR's <u>one-year funding website</u>. Students wishing to pursue a one-year medical student research fellowship from a Yale-administered fund must complete RCR training and obtain an <u>ORCID iD</u> to uniquely identify their scholarly products.

Deadlines

Summer Research Deadlines. Because these deadlines usually fall amidst other important deadlines and

exam dates, students are encouraged to start on their applications early and to plan accordingly.Students who are unable to meet either deadline should contact their Departmental Thesis Chair for an extension. The 2023-2024 summer research deadlines are currently being updated and will be posted shortly.

Short-term Research Deadlines (2023-2024). Please submit these applications to the Departmental Thesis Chair two weeks prior to the OSR deadline to allow sufficient time for review and processing. Students must apply prior to the start of their research. No electives, clerkships or vacations may be taken during the proposed research period. In order to be eligible, students must have entered their research time into Medhub. To comply with funding guidelines, students cannot be reimbursed for research that was done prior to an application period which was not pre-approved by OSR. Research must be a minimum of 4 consecutive weeks.

- 1) August 4, 2023 (Research Sept., Oct., Nov.)
- 2) November 3, 2023 (Research Dec., Jan., Feb.)
- 3) February 2, 2024 (Research Mar., Apr., May)
- 4) May 5, 2024 (Research Jun., July, Aug.)

One year-funding deadlines

The numerous one-year funding opportunities have varying deadlines which can be found <u>here</u>. External sponsors have deadlines occurring throughout the year. External funding websites contain links to numerous funding opportunities. These applications require administrative coordination from the mentor's department to meet Yale's internal processing deadlines, which generally precede those of the sponsor by up to 7 business days. Students interested in applying for an external funding award should discuss these plans with their mentor and contact OSR the earliest possible date. Additional information can be found <u>on the OSR website</u>.

A note on the financial implications of stipends. Students should be aware that stipend support provided during the summer, ATP, and fifth year has the potential to offset financial awards and should discuss their specific situation with the financial aid office. In addition, all stipends provided by OSR may be considered taxable income by the IRS. Yale provides the following <u>information for graduate and professional students</u>. Students are directed to meet with a qualified tax professional for questions related to tax implications of their stipend support.

Funding for Research Performed Outside Yale University

Some students wish to conduct in-person research at an institution other than Yale. OSR allows this, but students should be aware of the following.

First year students. There are many reasons why it is preferable for MS1s to conduct their summer research under the mentorship of a Yale faculty member. Close to 3,000 YSM faculty members are qualified to act as mentors. These individuals' understanding of the Yale system will maximize the student's opportunity to receive an excellent research education. Students working on campus also have to the numerous educational opportunities available to medical students such as Applied Principles of Research (APR) and seminars sponsored by OSR and YSM. Remaining on campus for the summer research experience will foster collaboration and a sense of community between classmates. Finally, funding in the summer of the first year is provided from training grants and Yale funds. Regulatory and institutional requirements for many of these sources stipulate that work be done with Yale investigators **Yale SCHOOL OF MEDICINE Office of Student Research** 22/39

with Yale oversight.

For these reasons, students are advised to begin their work at Yale with a YSM mentor in the summer of the first year. Students performing research at another institution are responsible for obtaining 50% of their funding from the other institution. Additionally, for several reasons it is still necessary to have a Yale sponsor before completing the arrangements elsewhere. First, the Yale faculty sponsor (and sponsoring department) will be responsible for approving the application for 50% funding from OSR. Second, in the event that work done elsewhere results in the MD thesis, this individual will serve as the local thesis sponsor and will have the thesis reviewed in their YSM department.

Obtaining funding from another institution: If the investigator at another institution is well resourced, they should demonstrate their commitment to the student by readily funding half or all of the stipend. If they are unwilling or unable to do so, then students should reconsider. Please note that students conducting their work at an outside institution should not be employed as research technicians or be expected to perform duties normally expected of an employee. Students should recognize that it is greatly preferable to begin the work at Yale in the summer of the first year.

Research at an outside institution done after the first year Students performing research at another institution other than the summer of the first year (3rd, 4th, or 5th year) can receive full stipend funding from OSR if the funding application is approved by a Yale faculty sponsor who commits to serving as the thesis advisor and submitting the work in their department. Because these projects often serve as the basis for the thesis (for which a Yale sponsor is required) students applying for external funding should identify a Yale faculty member who is willing to serve in this capacity.

This policy applies to both short-term funding and one-year medical student research fellowships, which for some pullout fifth year programs (Sarnoff, Yale Sponsored, etc.) can also be completed at other institutions.

Considering Yale-based Summer and/or Thesis Research Outside of the Medical School A student may wish to perform research under the supervision of a qualified full-time Yale investigator who does not have a YSM faculty appointment. This type of arrangement is acceptable and requires that a full time YSM faculty member serve as a faculty sponsor. The same regulations concerning the dates of submission and review by the appropriate Departmental Thesis Chair apply to this situation. In the case of summer projects, the YSM sponsor will be responsible for approving the proposal for funding, serving as the "host" department, and ensuring regulatory approval. In the case of the thesis, the YSM faculty member will be responsible for reviewing the thesis progress with the student, reviewing the written thesis, and providing faculty approval. The thesis will be reviewed by the Department Thesis Committee of this faculty member's department. This faculty member will also be signing off on funding applications applications (if applicable).

ONE YEAR MEDICAL STUDENT RESEARCH FELLOWSHIPS

YSM offers all medical students the opportunity to pursue a fifth year of medical school devoted exclusively to research funded by a formal One Year Student Research Fellowship. This Student Research Fellowship Program is facilitated by waiving tuition for the extra year and by the provision of a limited number of stipends that can be paid to students. These stipends are available on a competitive basis and students are eligible to apply after completion of their clinical rotations. One year fully funded fellowships administered by OSR require a YSM faculty mentor. Furthermore, because these experiences often serve as the basis for the YSM thesis, students applying for external fellowships through mechanisms other than **Yale SCHOOL OF MEDICINE Office of Student Research** 23/39

OSR (NIH,Sarnoff) are strongly encouraged to identify a Yale faculty member to serve as their sponsor and local mentor. Information can be found <u>here.</u> Currently available funding sources include but are not limited to: YCCI Multidisciplinary Pre-Doctoral Training Program, Sarnoff Foundation, National Institutes of Health, American Society of Hematology, Physician Scientist Support Foundation, and Yale sponsored funding. A directory of external funding opportunities is maintained on the OSR website. Because these grants are administered through Yale, the mentor's pre-award team in the Office of Sponsored Projects invests significant administrative effort to prepare applications and often requires letters of support and other documents from OSR. Therefore, students considering external research support should reach out to OSR as soon as they begin to contemplate the process. All stipends are paid directly to the student, considered taxable income, and may impact financial aid. Any questions regarding tax implications should be referred to a qualified tax specialist. Questions regarding financial aid should be referred to that office.

ADDITIONAL FUNDING

Research Costs

It is expected that costs of mentored research projects will be supported by the mentor's research program. Should MD students require additional support for which mentors lack funding, they may receive funding of up to \$1000 per academic year (July – June) from the Lowe and Levy endowments. Applications can be found <u>here.</u>

Conference Travel

Students enrolled in the MD program can receive up to \$700 in support for reimbursement of up to 50% of travel costs to present their research at one scientific conference per academic year (July – June). The policy is currently being re-evaluated and is subject to change. Funding instructions, guidelines, restrictions, and applications can be found <u>here</u>. Students are responsible for the remainder of travel costs. In past years, some students have reduced this portion through funds from their mentor, conference-specific travel awards, or other sources. Students should note that OSR operates under the governance of Yale's financial policy and cannot reimburse third party charges.

JOINT DEGREE PROGRAMS

Joint MD/MHS Degree

Yale School of Medicine and the Office of Student Research offer a joint degree, the MD/Master of Health Science (MD/MHS). Students enrolled in this degree must complete specific coursework and perform research under the guidance of a three-person MHS committee. MHS research also forms the basis for the MD thesis and is subject to the MD thesis regulations outlined later in this document. The MD/MHS degree adheres to academic credit hour accreditation requirements set forth by the New England Commission of Higher Education (NECHE).

Requirements:

1. Students must meet all YSM criteria to enroll in the MD/MHS dual degree program. These requirements, which can be obtained from the academic advisors and/or the OSR website (here) include having taken and passed both Step 1 and Step 2 CK by June 30 of the academic year preceding MHS matriculation. In the event that a student takes the exam by this deadline but subsequently receives a non-passing score, they will be deemed ineligible and administratively

withdrawn.

- 2. Students must be enrolled in the one-year fellows program to receive academic credit for a minimum of 30 credit hours of full time research. The one-year fellowship also provides a stipend and a small amount of financial support for research or travel.
- 3. Research conducted in the fifth year is the centerpiece of the MD/MHS degree. This project serves as the basis for the MD thesis and is governed by the regulations concerning content, organization, submission dates, and approval process outlined below (see "Formal MD Thesis Requirement").
- 4. The student must develop a research proposal and supervisory team comprised of the project mentor and ≥2 MD/MHS committee members that operates similarly to a PhD dissertation committee. This plan and its members must be approved by the Office of Student Research and the MD/MHS Advisory Committee.
- 5. The MD/MHS degree requires the completion of specific coursework and professional development activities. Unless public health concerns mandate virtual sessions, in-person attendance is required.

Required Courses and Activities

Listed below are the required courses for both the Clinical Research pathway and the Laboratory/Translational pathway. Please note that students must attend at least 80% of each required course in the chosen pathway to meet the requirement for the MHS degree. **In order to meet course credit requirements, these courses are in-person and must be taken during the 5th year**. All MD/MHS students must complete a minimum of 30 credit hours, comprised of a combination of coursework and research time, to meet MHS degree requirements. Starting with 2024 matriculants, MD/MHS requirements will be tracked in the Medtrics dashboard platform and additional coursework may be added.

1) Clinical Research Pathway required courses

- IMED 645: Introduction to Biostatistics (2 week summer course; 2 credit hours)
- **IMED 625:** Principles of Clinical Research (2 week summer course; 1.33 credit hours)
- Sect Ed 501: Responsible Conduct of Research (RCR) (academic year course, 6 sessions of approximately 2 hours each; 0.24 credit hours) OR IMED 630: Ethical Issues in Biomedical Research (Fall semester, weekly sessions of 1.5 hours each; 1 credit hours).
- An elective course may be added if desired (2 to 3 credit hours)

2) Laboratory/Translational Research Pathway required courses

- IMED 645: Introduction to Biostatistics (2 week summer course; 2 credit hours)
- Sect Ed 501: Responsible Conduct of Research (RCR) (academic year course, 6 sessions of approximately 2 hours each; 0.24 credit hours) OR IMED 630: Ethical Issues in Biomedical Research (Fall semester, weekly sessions of 1.5 hours each; 1 credit hours).
- An elective course may be added if desired (2 to 3 credit hours)

- 3) Both Tracks: Dedicated Research Time: The cornerstone of the MD/MHS degree program is an intensive mentored research experience culminating in the thesis. Matriculants are expected to dedicate the vast majority of their time to program-related research activities during the one year, full-time program. Matriculants can meet these research credit hour requirements by registering for research time in MedHub. MD/MHS students generally complete 35-45 credit hours of mentored research (note: one credit hour= 45 hours of full time research activity), depending on courseload.
- 4) **Both Tracks:** Participation in monthly seminars, journal clubs, Leadership in Biomedicine lectures and dinners, and other announced activities to support professional identity formation and cohort building throughout the MHS year.
- 5) **Both Tracks**: Participation in Student Research Day as a Poster Presenter and attendance at the entire Research Day program. 2024 Student Research Day will be held on May 7, 2024.

Joint MD/MPH Degree

For students in the MD/MPH Program, one thesis satisfies both degree requirements, provided it is approved and carried out under a Yale faculty member of the Department of Epidemiology and Public Health and is in an appropriate, health-related subject area. The same regulations concerning content, organization, and dates for submission of the MD thesis and review by the appropriate departmental committee will apply.

Joint MD/JD Degree

YSM has a formal relationship with the Yale Law School to allow students to seek degrees from both schools. A focused MD thesis, answering a significant question of medical relevance and meeting all requirements of the standard MD thesis, is required for the MD portion of the degree.

Joint MD/MBA Degree

The purpose of the joint-degree program in medicine and management is to develop clinician-managers capable of pursuing careers that balance delivery of patient care with sound management in a changing healthcare environment. The joint degree program normally requires five years of study and simultaneous award of the degrees of Doctor of Medicine and Master of Business Administration at the conclusion of the five-year period. A focused MD thesis, answering a significant question of medical relevance and meeting all requirements of the standard MD thesis, is required for the MD portion of the degree.

Joint MD/MDiv Degree

Students who have matriculated into YSM's MD program may apply to the Divinity School for admission to a combined program leading to the degrees of Doctor of Medicine and Master of Divinity. The joint program is tailored to the individual interests of students seeking professional education and training in a theological understanding of the self, society, and work; in bioethics; in international health and missions; in hospice or similar patient-care facilities; or in academic work in teaching, counseling, and chaplaincy. A focused MD thesis, answering a significant question of medical relevance and meeting all requirements of the standard MD thesis, is required for the MD portion of the degree.

RESPONSIBILITY OF FACULTY MENTORS

Overview. Role modeling and supervision during formative years are critical to success. Therefore, OSR encourages a close working relationship between the student and faculty research mentor. Best practices for mentor-mentee relationships are addressed in RCR starting in Fall 2023. Practically, the faculty advisor is responsible for providing the research infrastructure (space, equipment, supplies, data, cohorts, etc.). In order to ensure and support high quality research mentorship, the Yale Center for Clinical Investigation offers formal training based on the curriculum for the Center for the Improvement

of Mentored Experiences in Research. In addition, OSR directs all mentors to the "Optimizing the Practice of Mentoring," an open source online curriculum offered by the Clinical and Translational Science Institute at the <u>University of Minnesota</u>. OSR is working with YSM to develop guidelines governing the research mentoring of medical students. The below list is not intended to be all inclusive but, rather, presents the most critical responsibilities.

Specific responsibilities of mentors

- 1. Faculty members should adhere to high standards of ethical and professional conduct and follow all institutional policies and procedures
- 2. The faculty mentor should orient the student to a feasible question that can be addressed within the available time. This goal usually requires multiple meetings with the student, culminating in a project, protocol, and plan.
- 3. The faculty mentor should be prepared to provide formative and summative feedback and complete assessments to support progress towards educational program objectives
- 4. The student should develop with the faculty mentor their own project (although other individuals may participate) and should eventually be encouraged by the faculty mentor to be first author on abstracts and publications.
- 5. The student should not be assigned as a research technician to accomplish someone else's project in the lab, as a clinical research assistant on a clinical trial, or to duties lacking pedagogical merit.
- 6. The faculty mentor should invest sufficient time in the student, including weekly meetings to discuss results and, where necessary, help to focus (or refocus) the direction of the project.
- 7. The faculty mentor is responsible for all research expenses (i.e. space, resources, and facilities) and the supervision of the student's work. The faculty member is responsible for assurance of compliance with all relevant research regulations, including but not limited to addition of student to all relevant protocols, addition of the student to the <u>EHS</u> <u>Integrator</u> (if relevant), compliance with data security procedures, as well as for arranging student's research access to theelectronic medical record and other data resources.
- 8. The faculty mentor must review, approve, and sign the application for funding prior to submission to the Department Thesis Chair
- 9. In the case of the medical student thesis, the faculty mentor is the first reviewer and provides the initial approval of the thesis as submitted for graduation.
- 10. The faculty mentor should plan to attend Student Research Day activities which is currently scheduled for May 7, 2024.

MD THESIS REQUIREMENT: PREPARATION, AND APPROVAL PROCESS

Thesis Preparation and Approval

Preparation for thesis submission begins in the summer of the fourth year. At this time, timeline and practices are posted to the OSR website, distributed via email, and reviewed with students in class meetings. Because thesis approval is a lengthy process involving three levels of review, students are encouraged to manage their time well and start writing their first draft early in the fall semester of their final year of medical school. Starting in AY2024 the thesis approval process will be tracked in Medtrics dashboard.

July: OSR website is updated, thesis deadlines are distributed via email to all students in the graduating class, and an informational session is held. Students should be on track to complete their thesis research by mid-fall. Any student anticipating a challenge in this regard should contact OSR as soon as possible. By early August, all students expecting to graduate in May must submit their tentative thesis title and advisor to the Medtrics dashboard. OSR will contact all thesis advisors to confirm this role and to provide information and expectations regarding the thesis process. Students missing this deadline, or whose mentors express concern regarding the student's progress, will be referred to the Progress Committee to ensure adequate support for this graduation requirements.

August – December: Students should finalize research and draft their thesis. As the semester progresses, activities should shift from the data generation/analysis to thesis writing. Students should do their best to complete the first draft of the thesis by mid-late December. Because students are also involved in the residency application and interview process, they are discouraged from starting new projects at this time.

December – January: This period is devoted to reviewing and editing of thesis draft that is ultimately approved by the faculty mentor and submitted by the student to the Thesis Chair of their sponsoring department. The YSM faculty advisor will be asked to complete a thesis assessment that evaluates the student's performance on YSM's research-related educational objectives and provides meaningful summative feedback via the Medtrics dashboard.

January – March: The Departmental Thesis Chair coordinates thesis review by external reviewers. An "external reviewer" is defined as an individual who is not directly involved in the project. This individual may be a Yale faculty member internal/external to YSM or may hold a faculty appointment at an outside institution. This reviewer reads the thesis, completes the assessment, provides meaningful summative feedback, and makes recommendations for any required changes to the thesis. Departmental Thesis Chairs review assessments, notify students of departmental approval, and transmit these approvals to OSR. These assessments and approvals will be managed via the Medtrics dashboard.

March: Theses and their associated assessments undergo school-level review by OSR via Medtrics. Students receive YSM approval of their thesis along with summative feedback obtained during the review process. Students incorporate any required changes into their thesis and upload to the Yale Medicine Thesis Digital Library/Eli Scholar via the ProQuest platform.

April: OSR confirms that theses have been deposited into the Yale Medicine Thesis Digital Library and the YSM registrar receives the names of students who have completed the thesis requirement.

Thesis Deadlines for the 2023-2024 Academic Year

MD Students: OSR has worked with the Dean's Office and other educational stakeholders to establish deadlines for theses submitted in partial fulfillment of the requirements for graduation in May 2024. The deadlines ensure that students have sufficient time to complete their theses and that there is sufficient time for rigorous assessment and revision before final approval. These deadlines are strictly followed. Students are strongly encouraged to submit their theses <u>well before</u> the Class of 2024 Thesis Deadlines provided below. This timeline provides students, advisors, and sponsoring departments sufficient time for useful review and revision. It should be recognized by all concerned that the integrity of the thesis requirement and effective, rigorous review requires adherence to these deadlines. OSR will hold periodic zoom "Class of 2024 Thesis Check-in Sessions" and will distribute reminder emails with more detailed instructions as these deadlines approach.

Class of 2024 Thesis Deadlines – MD Students		
August 4, 2023*	Deadline for students to provide information	
	regarding thesis title and advisor to OSR	
August 4, 2023 – December 22, 2023	Student finishes research and writes thesis draft	
December 22, 2023 – January 2, 2024	Recommended date by which student provides	
	thesis draft to thesis advisor. Students should	
	communicate with their advisor to determine a	
	mutually agreeable date.	
December 22, 2023 – January 19, 2024	Advisor meets with student to review thesis.	
	Student makes revisions and provides advisor with	
	edited version. The revised thesis then receives the	
	advisor's approval for submission.	
January 19, 2024*	Thesis formally approved by advisor and student	
	submits to Departmental Thesis Chair for review	
	and approval.	
January 19, 2024 – March 1, 2024	Thesis undergoes Departmental review and	
	assessment, Thesis Chair provides thesis approvals	
	to OSR, and student receives notification of thesis	
	approval from Department.	
March 1-22, 2024	OSR reviews theses, assessments, and provides	
	formal YSM approval. Student receives notification	
	of thesis approval and feedback from OSR.	
	Information for ProQuest upload will also be	
	provided at this time.	
March 22-29, 2024*	Student makes any requested changes to thesis and	
	submits the approved, final version of thesis to the	
	library via ProQuest (all students meeting the	
	above deadlines.)	
*Students missing the August 4 th , January 19 th , and/or March 29 th deadlines will be referred		
to the Progress Committee to ensure they receive adequate support to make progress towards		
this graduation requirement. Students missing the January 19 th and/or March 29 th deadlines		
will be ineligible for thesis prizes at graduation.		

Extensions beyond the above thesis deadlines will be granted only for special circumstances and <u>must</u> have the approval of the student's thesis advisor, academic advisor, and the Departmental Thesis Chairperson. Students missing the August 4th, January 19th, and/or March 29th deadlines will be referred to the Progress Committee to ensure they receive adequate support to make progress towards this graduation requirement. In the event of an extension, if granted, the following ABSOLUTE Class of 2024 Thesis Extension Deadlines will apply:

Class of 2024 MD Thesis Extension* Deadlines		
Students missing either of these deadlines will be unable to graduate in 2024.		
March 22, 2024	For those students receiving thesis extensions, this	
	is the last date for the thesis to be formally	
	approved by advisor and submitted to	
	Departmental Thesis Chair for review and	
	approval.	
April 21, 2023	For those students receiving thesis extensions, this	
	is the last date for submission of an approved, final	
	version of thesis to the library via ProQuest.	
*All late theses require an extension. The Advisor needs to request the extension (in writing		
via email) before January 19, 2024.		

MD/MHS Students: Consistent with degree requirements, MD/MHS students must present their thesis to their three-person committee prior to the January 19th deadline. Students are encouraged to start arranging the date of this committee meeting in the fall to avoid unanticipated delays. Starting in AT2024, the MD/MHS process will be tracked in the Medtrics dashboard.

Class of 2024 Thesis Deadlines – MD/MHS Students		
August 4, 2023*	Deadline for students to provide information	
	regarding thesis title and advisor to OSR	
August 4, 2023 – December 22, 2023	Student finishes research and writes thesis draft	
December 22, 2023	Recommended date by which student provides	
	thesis draft to MHS advisor and committee	
	members. Students should communicate with their	
	committee to determine a mutually agreeable date.	
December 22, 2023 – January 19, 2024	Student presents thesis to MHS committee.	
	Student makes revisions and provides committee	
	with revisions. Committee formally approves thesis	
	and completes assessment.	
January 19, 2024*	Student submits thesis to OSR.	
January 19-March 1, 2024	OSR reviews theses, assessments, and provides	
	formal YSM approval of thesis. Student receives	
	notification of thesis approval and any feedback	
	from OSR. Information for ProQuest upload will	
	also be provided at this time.	
March 1-29, 2024*	Student makes any requested changes to thesis and	
	submits the approved, final version of thesis to the	
	library via ProQuest (all students meeting the	
	above deadlines.)	
*Students missing the August 4 th , January 19 th , and/or March 29 th deadlines will be referred		
to the Progress Committee to ensure they receive adequate support to make progress		
towards this graduation requirement. Students missing the January 19 th and/or March 29 th		

deadlines will be ineligible for thesis prizes at graduation.

MD/PhD Students: A different process applies to students in the MD/PhD program. For students enrolled in the combined MD/PhD Program, the dissertation submitted to and approved by the Graduate School will satisfy the MD thesis requirement. Therefore, MD/PhD students who have already defended their dissertation and received their PhD should provide this information to OSR via the Medtrics platform.

To ensure compliance with YSM graduation deadlines, MD/PhD students in the class of 2024 who have not defended and submitted their dissertation to the Graduate School by the October 1, 2023, deadline will need to submit a copy of their dissertation directly to OSR via email by March 15, 2024. OSR will convene a committee to review the dissertation, obtain feedback, and provide approval for graduation. Please note that MD/PhD students must *also* defend and submit their dissertation to the Graduate School no later than March 15, 2024, to meet the Graduate School spring degree deadline for conferral of the PhD degree. MD/PhD students who have not yet defended their dissertation should provide this information to OSR. If there are any questions about the process, please contact the MD/PhD Office.

THESIS AWARDS

The central role of the medical student thesis is to assess student's performance on YSM's research-related educational program objectives. As such, all students are expected to produce an excellent piece of scholarly work. In recognition of these achievements, OSR has worked to develop an awards process that celebrates the outstanding research done by YSM students without creating a competitive atmosphere. Hence, thesis awards are based on milestone-based assessments submitted by mentors and reviewers during the approval process, and internal review of the final thesis that was deposited into the Yale Medicine Thesis Digital Library. Consistent with all other graduation prizes, YSM MD Thesis Awards will remain confidential until they are announced in the YSM Commencement Program on May 20, 2024. While some departments may elect to confer thesis "honors" based upon their own internal review, this recognition is distinct from YSM graduation prizes and is not under OSR's purview.

REQUIRED COMPONENTS AND FORMATTING OF THE FORMAL MD THESIS

The formal thesis is presented as a digital document (PDF) during the graduation year. In general, one topic is appropriate for the thesis, but it is recognized that some students may have performed several projects in parallel under the supervision of their mentor. If the student elects to include more than one study in the thesis, it is recommended that an attempt be made to integrate thetopics into one coherent presentation. In rare cases where this goal cannot be achieved, it may be acceptable to divide the results section into different portions (or "chapters"). However, to be consistent with Yale formatting requirements, a thesis may not contain more than one abstract, introduction, statement of purpose, methods, results, and discussion section. It is not acceptable to submit a published or submitted manuscript in lieu of the thesis requirement. It must adhere to the following formatting and content requirements. These aspects of research are critical in making the work sound, error-free, and impactful for communities of interest. Recognizing that students may have uncertainty regarding how these guidelines relate to their thesis, OSR will be happy to answer any questions that may arise. Additionally, students may find it useful to consult the Equator reporting guidelines to enhance the quality and transparency of their theses. The Yale MD Thesis is a doctoral thesis that assesses research competencies as the basis for the conferring of a doctoral degree. Therefore, a minimum requirement of 30 pages (exclusive of title page, abstract, acknowledgements, table of contents, figure legends, references) is

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considered the minimum acceptable length.

Formatting

- 1) **Font:** 10-12-point font should be used.
- 2) **Line spacing:** Body paragraphs and tables should consist of double-spaced text. Single spaced text may be used within block quotations, footnotes, and bibliography.
- 3) **Margins:** 1.5-inch margins on the left with one-inch margins on the remaining three sides. These margins apply to text, full-page images and illustrations, and tables.
- 4) **Figures:** Illustrative information, schematics, and representative data should be included as figures. Each panel in a figure should be labeled. Legends should describe each panel in detail in a 9-point font or greater and positioned below the figure to which they refer. Figure legends do not count towards the 30-page minimum.
- 5) **Page Numbers:** Each page in the thesis should be numbered except the title page, abstract, acknowledgements, and table of contents. The numbering should start at page 1 of the first page of the Introduction and be placed either at the top or bottom center, or at the top or bottom right-hand corner, at least 1/2 inches from any edge.
- 6) **Minimal page requirement:** Most Yale MD theses average 40-80 pages of text. A minimum of 30 pages of text excluding title page, abstract, acknowledgements, table of contents, figures, legends, and references is required. Tables may count towards the minimum page requirement.

Required Components

- 1) **Title page:** Title should not exceed 100 characters including spaces between words. The title page is not included in the 30-page minimum.
- 2) **Abstract page:** As described below. The abstract is not included in the 30-page minimum.
- 3) Acknowledgements: Personal and faculty acknowledgements, grant support, departmental support, etc. The acknowledgements page is not included in the 30-page minimum.
- 4) **Table of Contents:** with page numbers for each section. The table of contents is not included in the 30-page minimum.
- 5) **Introduction:** A thorough, complete, detailed, critical review of the literature that contextualizes and cites the work of previous investigators. This section should describe the state of the existing knowledge, provide rationale for the study, identify knowledge gaps, and frame the contribution of the thesis to medicine. The introduction is included in the 30-page minimum.
- 6) **Statement of purpose:** Specific hypothesis if appropriate, and specific aims of the thesis. The statement of purpose is included in the towards the 30-page minimum.
- 7) **Methods:** Thorough description of valid and rigorous study design. The methods are included in the 30-page minimum.
 - i. **Student Contributions**: Describe in detail exactly which procedures, methods and experiments were conducted by the student and which procedures, methods and experiments, generation of data, or production of reagents, were performed by other members of the study team. It is not sufficient to state that this information may be mentioned elsewhere. It must be summarized here. It is recognized that students may often be

completing a portion of a larger work. A statement detailing precisely what was done by the student and what was done by others does not detract from the thesis but is necessary for academic honesty.

- ii. **Ethics Statement:** Include information regarding the ethical conduct of research.
- iii. **Human Subjects Research:** If relevant, include explicit information regarding HRPP approval and informed consent. If thestudy had a waiver of consent, this exception must be clearly stated. Information regarding inclusion of historically vulnerable populations as research participants should be included here.
- iv. **Laboratory Animals:** For studies involving laboratory animals, include an explicit statement regarding study approval from the Institutional Animal Care and Use Committee. Include information regarding the species, strain, sex, and age of laboratory animals in this section as well.
- v. **Methods Description:** Provide information regarding the materials and methods used in the study. Each method should consist of its subheading and paragraph and be described in detail that is sufficient to allow its replication by an investigator who did not participate in the study.
- vi. **Statistical Methods:** The last paragraph in this section should present the methods used to derive results. As needed, describe any data preprocessing such as transformation and normalization. Describe how outliers were defined and handled and present descriptive statistics as appropriate. The number of sampled units (ie, "n") and significance (ie, "P") should be reported for each statistical comparison. Continuous variables that are normally distributed may be presented as mean \pm standard deviation. Continuous variables that are asymmetrically distributed should be presented as median \pm interquartile range. All statistical tests should be clearly described and include information regarding testing level (alpha) and one- or two-sided comparisons. Corrections for multiple testing should be addressed and reported. Any novel or complex data algorithms should be clearly described and appropriately referenced.
- 8) **Transparent reporting of results:** All primary data related to the thesis topic should be presented. Important data should be enumerated in figures or tables. For ease of review, it is preferred that figures and tables be included in proximity to their callout in the text. Alternately, tables and figures can be presented separately after the discussion but, if possible, it is advantageous to the reader to include these components in the body of the results section, as occurs in research publications. The results section is included in the 30-page minimum.
- 9) **Discussion:** This section presents thorough and detailed interpretation and analysis of data, conclusions drawn, and framing of observations with the larger scientific literature. Limitations should be addressed, as should alternate interpretations and how the thesis may inform future studies in the field. Whenever relevant, a discussion of how the thesis may or already has meaningfully impact(ed) communities of interest should be included here. The discussion section is included in the 30-page minimum.
- 10) Challenges & Limitations: A brief discussion of methodologic, operational, and other challenges relevant to the research presented in the thesis. Please also include a brief discussion of how these challenges were addressed. Recognizing that all research projects
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have important limitations that readers should consider in interpreting the results, please include a brief discussion of the limitations relevant for the research. This section is included in the 30-page minimum.

- 11) **Dissemination:** Please include efforts made to share findings with the scientific community (through oral presentation, peer-reviewed publications, and other venues) and the larger community including patients. This section is included in the 30-page minimum.
- 12) **Figure References and Legends:** Figures must be cited sequentially in the text using Arabic numerals (for example, "Fig. 7"). Provide a short title (in the legend, not on the figure itself), explanation in sufficient detail to make the figure intelligible without reference to the text, and a key to any symbols used. Figures and legends are not included in the 30-page minimum.
- 13) **Tables:** All tables should be double-spaced, self-contained, and self-explanatory. Provide brief titles and use superscript capital letters starting from A and continuing in alphabetical order for footnotes. Tables and their legends are included in the 30-page minimum.
- 14) **References:** It is strongly recommended that students use bibliography software such as Endnote for reference management. References should be formatted according to New England Journal of Medicine Style. References are not included in the 30-page minimum.

It is acknowledged that theses in the area of medical humanities, ethics, history, and related fields may not obviously adhere to the above requirements. In this case, the thesis will likely replace the "hypothesis" with a "claim" based on evidence gleaned through literary, historical, and ethical research. The first paragraph of the Methods should still contain information about the student's contribution. The subsequent paragraphs should describe the artistic, literary, or historical databases and methods used to gather the "evidence" presented in support of and contrary to the central claim. The discussion and remaining sections are the same and the 30-page minimum applies. Students with questions regarding the best framing of their thesis should contact OSR.

INSTRUCTIONS FOR UPLOADING A PDF VERSION OF A MEDICAL THESIS

Upon receiving notification that the MD thesis has been approved as fulfilling partial requirement for Yale's MD degree, students should upload the thesis to the Yale Medicine Thesis Digital Library. Students will receive instructions at the time their thesis is formally approved. For reference, a high level overview is outlined below.

Yale Medicine Thesis Digital Library

Starting with the YSM class of 2002, the Cushing/WhitneyMedical Library and OSR have collaborated on the <u>Yale Medicine Thesis Digital Library</u> (YMTDL) project, publishing the digitized full text of medical student theses as a durable product of Yale student research accomplishments. Digital publication of theses ensures dissemination of the work to communities of interest, provides students with a formal citation for their thesis, and demonstrates the exceptional quality of student research and student-faculty cooperation at Yale. In 2006, the digital copy became a graduation requirement. Starting in 2012, alumni of the Yale School of Medicine were invited to participate in the YMTDL project by granting scanning and hosting permission to the Cushing/Whitney Medical Library, which digitized the Library's print copy of their thesis or dissertation.

Yale School of Medicine requires that the MD thesis be submitted to the YMTDL. This submission is accompanied by a completed "Yale School of Medicine Digital Thesis Depositor's Declaration Form" which is found within the ProQuest site.

Submitting a thesis via the ProQuest website: Yale SCHOOL OF MEDICINE Office of Student Research

Detailed Instructions: https://www.etdadmin.com/main/resources?siteId=323

Logging In: <u>http://www.etdadmin.com/cgi-bin/student/etd?siteId=323</u>

The electronic thesis submission process in ProQuest provides step by step submission instructions. Questions may also be directed to Kayla Del Biondo in the Medical Library (kayla.delbiondo@yale.edu).

A few things to note: the ETD Administrator software is a 3rd party product that YSM licenses from ProQuest. Because this vendor is unaffiliated with Yale, OSR and Yale University Libraries do not have control over its policies or processes. The ProQuest Dissertations and Theses Global database is a subscription resource that collects dissertations and theses from multiple countries and a range of academic specialties. This collection is then made available to subscribers. When students choose to make their thesis publicly available, the full-text will appear in this database and users will be able to read, save, and download the text.

EliScholar is a digital platform for scholarly publishing provided by the Yale University Library (YUL). While it is supported by third party software, EliScholar is maintained by YUL and offers more flexibility in uploading and managing theses. The option selected for thesis release in the ETD Administrator system will apply to both ProQuest Dissertations and Theses Global and EliScholar. All theses are available to the Yale community (individuals with a NetID and password and users physically present at a library facility on campus) upon publication. A limited release of approved theses to the awarding institution's user community is common practice.

More detailed instructions will be provided at the time of thesis approval in March 2024.

AVOIDING THE RISK OF COPYRIGHT VIOLATION WHEN SUBMITTING THE MD THESIS

The MD Thesis represents an academic milestone. Thesis copyright exists from the time the work was created in digital form. Every article, book, or web page used in conducting research and writing the thesis is also protected by copyright. All downloaded research articles and passage citations are also scholarship that is protected by thelegal concept of fair use. A basic understanding of copyright protections and fair use is found at <u>www.copyright.gov</u>. Yale University also provides a guide to copyright protection and fair use <u>here</u>.

Section 107 of the U.S. Copyright Law describes how to determine if a particular use of copyrighted material is fair. However, the distinction between what is fair use and what is infringement is not always clear or easily defined. Copying an image from an academic e-journal and citing the source does not substitute for obtaining permission to reproduce the image. Many publishers use <u>www.copyright.com</u> to grant reproduction rights of their articles to authors.

ProQuest/UMI and the Yale Medicine Thesis Digital Library may elect not to distribute any thesis that lacks evidence that permission or reproduction rights have been secured. Providing evidence of permission or reproduction rights is a student author responsibility. Examples encountered in MD Thesis research that require documentation of reproduction rights include but are not limited to:

- 1) Sections of published survey instruments or questionnaires.
- 2) Complete journal articles or other complete scholarly works [Note: Many publishers such as Elsevier allow graduate student authors of a journal article published prior to graduation to reproduce their article in a thesis].
- 3) Image, graphic, or pictorial works from publications where the author has transferred copyright to the publisher, a common occurrence.

The safest course is to avoid using published images without obtaining permission. It is almost always possible to cite a source and expect that readers can find the figure, chart, or image in the published version of the referenced work. Research faculty who transfer copyright to a publisher of their article are no longer the copyright holder and are unable to grant permission for reproduction. To circumvent this issue, the student or mentor may be able to obtain unpublished images from their group's image collection.

When it is impracticable or prohibitively expensive to obtain permission through the publisher or the Copyright Clearance Center (https://www.copyright.com/) students should avoid using that material, unless they have obtained a written legal opinion that fair use would apply to the situation. Neither the Office of Student Research nor the Yale Library can supply legal advice on copyright and fair use. If there is any doubt, it is advisable to consult the Yale University Office of the Vice President and General Counsel at (203) 432-4949.

Students may have concerns about publishing their work in the public domain for reasons such as copyright, content, or intellectual property. These students have several courses of action. One is to select an alternate topic. The other is to place the thesis under permanent embargo at the time of upload into the Yale Medicine Digital Thesis Library. In either case, students be aware of these issues as they plan their thesis and reach out to OSR for additional information.

OSR will offer a thesis copyright session for the Class of 2024 in fall of this year.

Abstracts of MD Theses

Standardized format for the abstract of each MD thesis is required. This format must be followed for all abstracts published in the Yale Medicine Thesis Digital Library. These abstracts will not be reviewed for content. It is the responsibility of the student investigator and the faculty advisor to prepare the abstract. Faculty sponsors provide approval of the abstract when they approve the final version of the thesis. These abstract instructions are to be used for the digital library submission.

- 1. Abstracts should be formatted with 1.5 inch margins on the left and 1-inch margins on the remaining three sides.
- 2. Abstracts may be no more than 800 words in length, not including title and author information. The entire abstract, including title page, must be double-spaced and should be no more than two pages in length.
- 3. Titles should be brief, clear, and carefully chosen. The title should not exceed 100 characters including spaces between words. Capitalize the entire title, using no abbreviations.
- 4. Authors' names are to be written in full, omitting degrees. The student author's name shallbe first. If the faculty sponsor also qualifies as an author, their name should be last. If the faculty member has been only a sponsor, his or her name should appear in parentheses after the name(s) of other authors as follows: "(Sponsored by...)". Other collaborators should be listed after the student's name and before the faculty sponsor's name. Immediately following the faculty sponsor's name, designate section (if any), departmental affiliation, institution, city, and state (Yale University School of Medicine, New Haven, CT)(see examples).
- 5. For thesis work performed at another institution, designate the senior author's departmental and institutional affiliation. In parenthesis, indicate the Yale faculty sponsor and institutional affiliation with the phrase: "Sponsored by..." (see examples).
- 6. Organize the body of abstract as follows:
 - a. A statement of the hypothesis or goals and specific aims of the study.
 - b. A statement of the methods used.

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- c. A summary of the results presented in sufficient detail to support the conclusions.Include actual values with statistics, if appropriate.
- d. A statement of the conclusions reached.
- e. Do not use subtitles; e.g., methods, results.
- 7. Do not include graphs, references to other publications, or acknowledgement of any research grant support. A single short table of results can be used if appropriate.
- 8. Abbreviations may be used in text only if defined initially by placing them in parentheses after the full word (or phrase) first appears in the text. Abbreviations may not be introduced in the title.
- 9. Non-proprietary (generic) names are required the first time a drug is mentioned, written in small letters. Proprietary names are always capitalized, e.g., acetazolamide (Diamox).
- 10. Completed abstracts must be approved by faculty advisor.

Thesis Title Page Format

(Full Title of Thesis)

A Thesis Submitted to the Yale University School of Medicine in Partial Fulfillment of the Requirements for the Degree of Doctor of Medicine

by

(Legal name of author) (Year of degree)

Examples of Abstract Formatting

1) Thesis completed under supervision of a YSM Mentor

INCIDENCE OF SUPRAVENTRICULAR ARRYTHMIAS IN AN AGING POPULATION.

Erica L. Herzog and Sarwat I. Chaudhry. Section of Cardiology, Department of Internal Medicine, Yale University, School of Medicine, New Haven, CT.

2) Thesis completed under supervision of a Yale faculty member who does not hold an appointment at YSM, where the faculty advisor is not a co-author:

ELECTRICAL IMPULSES IN ENGINEERED HEART TISSUE

Erica L. Herzog and Sarwat I. Chaudhry (School of Engineering, Yale University, New Haven, CT). (Sponsored by Jessica Illuzzi, Department of Obstetrics and Gynecology, Yale University, School of Medicine).

3) Thesis completed at an outside institution:

INCIDENCE OF SUPRAVENTRICULAR ARRYTHMIAS IN AN AGING POPULATION.

Erica L. Herzog and Sarwat I. Chaudhry. Section of Cardiology, Department of Internal Medicine, St. Elsewhere Hospital, Boston University, Boston, MA. (Sponsored by Jessica Illuzzi, Department of Obstetrics and Gynecology, Yale University, School of Medicine).