

Special Communication

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Clinical Research
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An interprofessional model for training the next generation of physician-researchers

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Abstract

The potential for physicians, clinicians, and health professionals to contribute to the advancement of medical therapies through clinical research is significant. Yet, a lack of exposure to, or practical training in, the conduct of clinical research can inhibit health profession trainees from considering research careers, thus perpetuating the already limited influx of new talent. To enhance the sustainability of career pathways into research for all trainees, including those from traditionally underrepresented communities, trainees must experience early exposure to research concepts through robust training and hands-on opportunities. In 2015, the Duke Office of Clinical Research created a Research Immersion elective for Duke's Master in Biomedical Sciences program, which prepares students for additional health professional training. The course trained students through didactic and practical experiences, with a unique interprofessional mentorship team including both principal investigator and clinical research professional mentors. Following eight cohorts of iterative course optimization, students' confidence increased in all 24 research competencies assessed. A cross-sectional analysis of post-course outcomes in May 2024 revealed 40.4% of students had continued in research after the program and 60.6% had continued their health professions education. We attributed this success to applied learning and clear expectations and guidelines to support the mentor-student relationship.

Introduction

It is well documented that the clinical and translational investigator and clinical research professional (CRP) workforces alike struggle to recruit and maintain members, especially from minoritized communities [1,2]. While trainee and junior faculty involvement in research is an essential component of an effective physician-researcher career pathway, these individuals often lack fundamental knowledge of the skills, practices, and regulations required for study conduct as defined by the Joint Taskforce for Clinical Trials Competencies (JTFCTC) [3,4]. Individuals from underrepresented communities identify additional obstacles to pursuing research careers, including concerns about funding disparities and financial security, family obligations, and the lack of career guidance [5,6].

NIH institutional grant programs have sought to address sustainable pathways into research (T mechanisms), funding opportunities (K mechanisms), and workforce diversity (diversity supplements). However, even with adequate funding, early career researchers may still lack the skills needed to conduct research successfully [7]. Thus, significant gaps in clinical research training for those pursuing research careers remain.

Nearing et al. identify continuous training, effective mentorship, and outcomes assessment as essential strategies to promote recruitment and retention of talented researchers and create diverse pathways into research careers [8]. These authors and others emphasize early student engagement in research as crucial for career pathways, requiring opportunities for direct contribution to research goals, contextual understanding, and personal and professional fulfillment [9,10]. In addition, effective career pathways must adapt to the needs of a more diverse population of trainees by emphasizing skill and talent development, along with academic or age-related milestones [11].

To address gaps in early career research training, the Duke Office of Clinical Research (DOCR), in collaboration with the Duke University School of Medicine, developed an innovative course focused on clinical research conduct for students intending to pursue health careers. The DOCR Research Immersion (RI) course is one of several electives, called

“selectives,” offered by the Master of Biomedical Sciences (MBS) program, a 38-credit, 10-month degree program that prepares post-baccalaureate students to be competitive candidates for health professional programs and biomedical careers [12]. MBS is intentional in its approach to recruitment from traditionally underrepresented communities, including those of lower socioeconomic status, first-generation college students, and students for whom English is a second language. Program core courses are based on Duke’s MD preclinical curricula, while the selectives allow students to gain additional insight into diverse healthcare career paths and explore their interest in direct patient care, research, and the humanities. DOCR engaged with MBS with the goal of providing a diverse group of students the opportunity to learn about research conduct.

The RI selective is a 140-contact-hour (4-credit-hour) immersive research experience, enrolling 27% of all MBS students in the first eight years. Training, mentorship, and support are the foundational pillars of this selective, providing multidimensional learning opportunities through didactic sessions and interaction with an investigator mentor and their CRP team. Here, we describe the RI selective’s staffing, curriculum, and structure, examine the experience and outcomes for students and mentors, and discuss the successes, challenges, and lessons learned to inform implementation at other academic medical centers.

Materials and methods

Course development and structure

DOCR is housed within the Duke University School of Medicine and provides the navigation, tools, and training to support the conduct of clinical research by researchers at all levels [13]. At the MBS program’s inception in 2015, MBS leadership engaged DOCR to design a selective incorporating JTFCTC-defined clinical research competencies, specifically focusing on study conduct competency areas. We have enrolled up to 16 MBS students in the course, with no prerequisites or prior research experience required. The 14-week course starts in January (Figure 1A) and employs multiple means (lectures, facilitated discussion sessions, investigator-led presentations, mentored internship) to ensure learner engagement across 12 learning objectives (Figure 1B), addressing Bloom’s taxonomy levels for recognizing, understanding, and applying information [14]. The course combines didactic education with a semester-long internship with a research team, enabling students to generalize learning beyond the classroom and reinforcing competency development within a practical setting. Figure 1C summarizes information provided to students and mentors in advance of the term (Supplemental Digital Appendices 1 and 2).

Staffing

A core operational team (approximately 0.25 FTE combined dedicated effort) manages the RI selective. The core team (SB, TS, JW, and SF) includes expertise in research conduct, project management, and health education and is supplemented by a larger team of staff and faculty subject matter experts representing multidisciplinary clinical and research specialties. This provides students with a comprehensive overview of research conduct. The faculty and CRP mentors provide instruction voluntarily in accordance with Duke’s academic mission.

Curriculum

The course curriculum (Supplemental Digital Appendix 3) is designed to provide students with foundational knowledge of clinical research conduct and enable them to function as an integrated member of a research team while introducing them to the broad diversity of Duke research. To expedite hands-on engagement with their projects, students complete pre-term online GCP courses and training in electronic medical record handling, study documentation, consent, and REDCap (Research Electronic Data Capture) [15]. Early in the semester, students attend once-weekly instructor-led classes on research conduct, ethics, and research governance taught by Duke staff and faculty in preparation for working in research at Duke. Additional sessions throughout the semester expose students to different types of research through “investigator highlight” lectures, and students explore topics related to research ethics through facilitated journal club discussions led by students.

Mentorship

The central experiential learning opportunity of the course is founded on interprofessional mentorship by faculty and research staff teams. Each student is matched with a principal investigator (PI) faculty mentor and incorporated into the mentor’s team as a contributing member (one student per mentorship team). These placements provide the foundation for a mutually beneficial student-mentor relationship with relevant applied learning opportunities. A diverse and evolving pool of mentors is maintained and recruited based on prior mentorship experience, therapeutic areas, and the ability of faculty research portfolios and teams to accommodate meaningful student involvement. Because front-line CRPs provide essential insight and guidance for the day-to-day conduct of clinical research projects, we recruit mentors with strong CRP support to create co-mentorship teams.

Mentor matching occurs after student enrollment in the course and before the start of the term. Students complete an intake survey to describe their therapeutic areas of interest. While we aim to match students with mentors based on students’ preferences, our priority is optimizing the mentorship experience by matching students with an effective and engaged mentor.

Mentors and teams identify ongoing clinical research projects in which the student can have an appropriate and active role while meeting program learning objectives. We discourage students and mentors from designing independent student projects, as the course time frame is not typically sufficient for the execution of an independent clinical research project. While mentors may provide students with authorship opportunities, as many students desire, this is purposefully not an expectation of our selective. We have seen that the pursuit of a manuscript during the four-month selective has significantly limited exposure to the full breadth of study conduct experiences and learning objectives.

Students spend 10–12 hours per week on their mentored research projects. Students’ involvement in research projects is task-based and intended to provide exposure to research conduct. Typical activities include screening, recruitment, and consenting of participants, data abstraction and entry, REDCap database design, secondary analysis, and Institutional Review Board (IRB) materials preparation. Mentors meet regularly with students to ensure that research activities are conducted with GCP, provide performance feedback, and offer guidance on project-related assignments. Mentors often provide opportunities for clinical shadowing and interact with colleagues and collaborators. Mentors submit

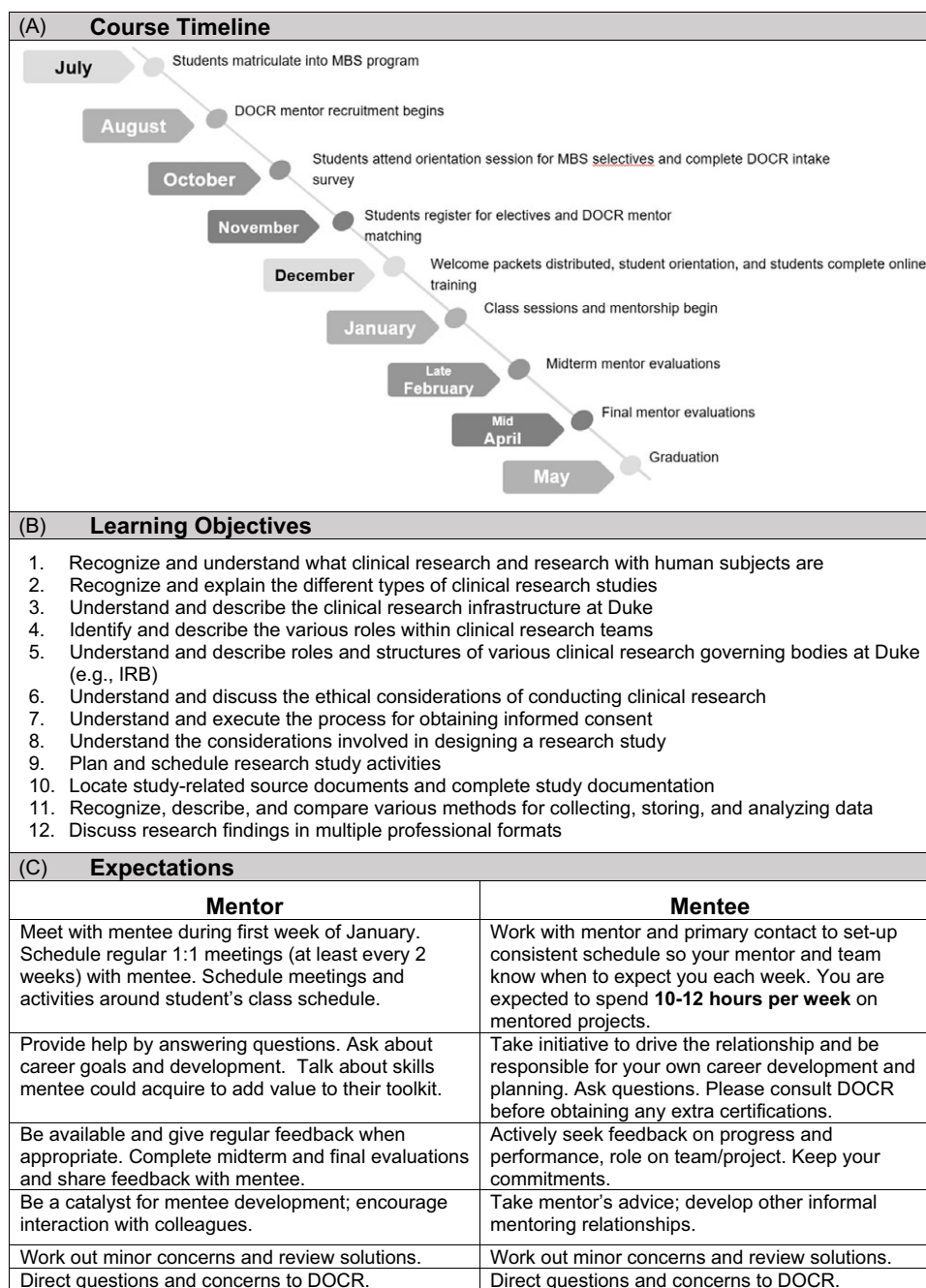


Figure 1. (A) Course timeline, (B) learning objectives, and (C) expectations; Duke Office of Clinical Research (DOCR), Master of Biomedical Sciences (MBS), Institutional Review Board (IRB).

mid- and end-of-term assessments of student performance and share the feedback with their students.

Assignments and grading

Students' assignments are detailed in Supplemental Digital Appendix 3 and summarized below. We provide broad guidelines for the assignments that encourage student self-expression and ownership.

- Weekly journal entries, to describe their experiences and provide a qualitative assessment of progress related to course objectives;

- Mid-term abstract scientific writing exercise, to assess their understanding of and ability to describe the objectives, methods, expected outcomes, and clinical impact of their mentored project;
- Final presentation, to assess their ability to discuss their research project and evaluate their understanding of the larger context of their role in the project.

We manage assignments and grading in CANVAS using standard rubrics. The course grade is calculated based upon the following scale: 30% didactic, 50% research internship (mentor assessments plus journal entries), 5% mid-term abstract, and 15% final presentation.

Mentor and student support

We maintain frequent communication with students and mentors throughout the semester. First-time mentors receive 1:1 onboarding and orientation in advance to review expectations and desired activities for mentors and students. When issues arise, we meet with the parties involved to try and resolve any impasse and, when necessary, seek consultation with the MBS program for guidance relative to program regulations and expectations for students.

Data collection and course evaluation

We use REDCap to collect all course evaluations, assessments, and feedback. REDCap is a secure, web-based software platform designed to support data capture for research studies, providing (1) an intuitive interface for validated data capture, (2) audit trails for tracking data manipulation and export procedures, (3) automated export procedures for seamless data downloads to common statistical packages, and (4) procedures for data integration and interoperability with external sources. This includes the collection of anonymous course feedback and pre- and post-course clinical research competency data from students to assess the efficacy of the course (exempt by DUHS IRB under protocol number Pro00086608, 08/14/2017). We employ a modified version of the Clinical Research Appraisal Inventory (CRAI) [16] to collect students' self-reported confidence in 24 selected domains of clinical research competency on a scale of 0 (No confidence) to 10 (Total confidence) pre-course and post-course (Supplemental Digital Appendices 4 and 5). To evaluate the relationship between course content and confidence, we collect students' perceived exposure to each competency area. Retrospective pre-course confidence is collected to assess whether pre-course confidence is overestimated when students have limited knowledge or competence in a domain (Dunning-Kruger effect) [17]. Separate REDCap surveys collect quantitative and qualitative data from mentors to evaluate mid- and end-term student performance (for grading) and mentor satisfaction (Supplemental Digital Appendices 6, 7, 8). Post-course short- and long-term outcomes data are collected by DOCR and the MBS program. Demographic data are collected from the Duke University Office of the Registrar.

Statistical analysis

We summarized demographics with frequencies and percentages. Using Excel and SAS Enterprise Guide 8.3, we conducted a series of statistical analyses (raw deltas, Cohen's *d* effect sizes, and paired *t*-tests) of the CRAI competency data to evaluate the differences between pre/retro-pre and post scores. Effect sizes are interpreted as small (0.2), medium (0.5), and large (0.8) [18]. Analysts reviewed student feedback responses and identified thematic categories, and an additional analyst coded the themes present in each response. We summarized mentor satisfaction data with frequencies and percentages and categorized professional outcomes data by frequency and percentage based on an analysis conducted in May 2024.

Results

Student demographics

A total of 95 students enrolled in the course between 2016 and 2023, and 94 of those students completed the course. The number of students per class ranged from 7 to 16, with a median of 12 students per year. Table 1 summarizes student demographics.

Table 1. Student demographics (MBS *N* = 359; DOCR RI *N* = 94)^a

Race	Total number of students	
	MBS Program	DOCR RI Selective
Asian	51 (14.2%)	20 (21.3%)
Black	112 (31.2%)	23 (24.5%)
Hispanic	48 (13.4%)	11 (11.7%)
Multi-racial	3 (0.8%)	3 (3.2%)
Native Amer Indian/Other Pac Islander	10 (2.8%)	2 (2.1%)
Unknown or not reported	14 (3.9%)	3 (3.2%)
White	121 (33.7%)	32 (34.0%)
Total	359 (100%)	94 (100%)

^aStudent demographic data were provided by the Duke Office of the University Registrar and are presented as they were collected by the registrar.

The race/ethnicity characteristics of the DOCR RI students are similar to that of all enrollees in the MBS program. Gender distribution reflects slight differences (DOCR RI: male 48 (51.1%)/female 46 (48.9%); MBS: male 148 (41.2%)/female 208 (57.9%)/unspecified 3 (0.8%)).

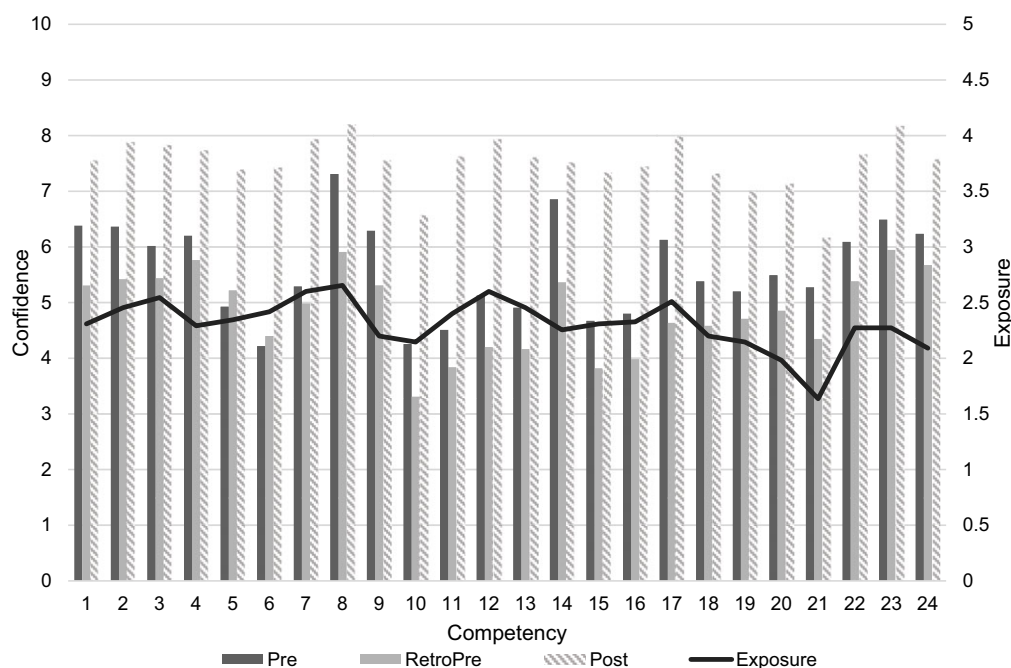
Self-rated clinical research competency

Students self-reported their confidence in 24 domains of clinical research pre-course ("actual pre"), retro-pre-course, and post-course, and their estimated "exposure" during the mentored rotation (Figure 2). Retro-pre- vs. post-scores demonstrated statistically significant increases in confidence across all competency areas as evaluated by paired *t*-tests ($p < 0.0001$). However, when comparing actual pre- vs. post scores, only "Adhering to a timeline for research projects" was found to have an insignificant change in scores ($p = 0.0693$), reflecting also a significant difference between actual pre- and retro-pre-scores ($p < 0.0001$). This suggests that students' understanding of research project timelines changed after experiencing the course.

Students showed an average growth in confidence of over 3 points for 8 competency areas (33%) and over 2 points for 21 competency areas (87.5%). The largest areas of confidence gained were articulating IRB role and function (11, 3.78 points) and reviewing key study documents (12, 3.73 points). The least confidence growth was shown in writing a literature review (21, 1.82 points) and orally presenting results (24, 1.89 points). Effect sizes were consistent: 11 and 12 had large effect sizes, 1.69 and 1.71, respectively, while 21 and 24 had medium effect sizes, 0.68 and 0.79, respectively. Although "Understanding regulatory guidelines and their impact on the conduct of research" was the fifth largest area of confidence gained (13, 3.44), it had the largest effect size of 1.75.

Student feedback

Students provided quantitative course feedback and completed five qualitative questions to identify the most useful and least useful aspects of the course, suggested improvements, opportunities for development or application of leadership skills, and additional comments. Some responses contained multiple themes.



- 1 Selecting a suitable topic area for study
- 2 Communicating a clear purpose for the research
- 3 Placing one's study in the context of existing research and justifying how it contributes to important questions in the therapeutic area or research field
- 4 Stating the purpose, strengths, and limitations of each study design (such as case reports, case controls, cross-sectional, longitudinal, epidemiological studies, randomized control trials, and clinical trials, etc.) and choosing the appropriate design to test a set of hypotheses
- 5 Recognizing which data collection and analysis methods are most appropriate to the study population and variable(s) of interest
- 6 Explaining how industry sponsored research and PI-initiated research are conducted at an academic research institution
- 7 Explaining the roles and responsibilities of various study team members and working interdependently to achieve study goals
- 8 Establishing and maintaining open lines of communication with mentors and study team members
- 9 Participating in generating collaborative research ideas
- 10 Using electronic medical records (MaestroCare) to facilitate patient screening and acquire project-related data
- 11 Articulating the role and function of an institutional review board (IRB)
- 12 Reviewing key study documents (protocol, consent form, etc.) to direct daily research operations
- 13 Understanding regulatory guidelines and their impact on the conduct of research
- 14 Adhering to a timeline for research projects (schedule of assessments, project milestones and deliverables)
- 15 Describing appropriate recruitment and retention methods used in clinical research
- 16 Applying appropriate processes for obtaining informed consent from research subjects
- 17 Describing ethical issues involved in conducting clinical research, including minority and vulnerable populations
- 18 Explaining the potential risks and other special considerations associated with different types of research (behavioral, clinical, etc) including how the HIPAA privacy rule applies to research
- 19 Constructing a plan for organizing and managing data files and research processes
- 20 Organizing a research report or a journal article including a reproducible description of methods and clear summary of results
- 21 Writing a literature review that critically synthesizes the literature relevant to your own research question
- 22 Discussing study findings, articulating the importance of your findings relative to other studies in the field
- 23 Designing visual presentations (posters, slides, graphs, pictures, etc.)
- 24 Orally presenting results at a meeting

Figure 2. Self-rated clinical research competency (pre, retro-pre, post); principal investigator (PI), Institutional Review Board (IRB), Health Insurance Portability and Accountability Act.

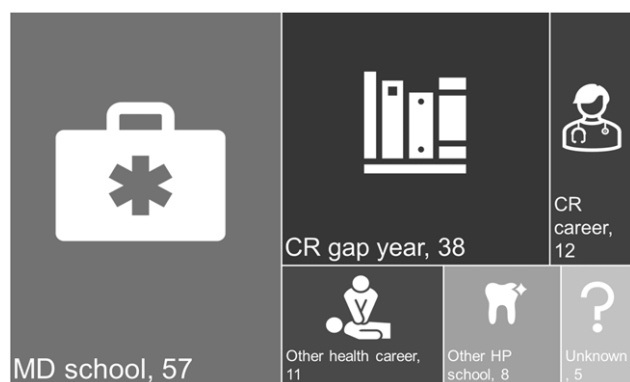


Figure 3. Professional outcomes of research immersion selective students 2016–2023; medical degree (MD), clinical research (CR), health professional (HP).

Post-course, 93.6% of 63 respondents reported they would recommend the mentored research experience to others. Students expressed gratitude for the course and their mentors and for the opportunities to develop new skills. Dominant themes for improvement included: course expectations (24%), specific didactic sessions (33%), mentor expectations and planning (35%), and repetitive assigned tasks (36%). Some students suggested lengthening the course to enable greater contributions to their mentored projects.

Mentor feedback

In addition to student performance assessments, PI and CRP mentors completed post-course evaluations of the DOCR selective. Nearly 95% of respondents agreed or strongly agreed that their mentee match was appropriate ($n=98$) and that their mentee contributed to their research ($n=97$), participated in day-to-day project operations ($n=97$), and demonstrated interest/concern toward their project ($n=97$). Nearly 95% of respondents indicated they would participate in the mentorship program again ($n=97$). Mentors favorably rated the timeliness (94%) and frequency (89%) of DOCR communications ($n=97$).

Post-course student placement and long-term outcomes

Figure 3 depicts the post-MBS short- and long-term professional outcomes of students enrolled in the selective through May 2023 ($n=94$). The categories included are not mutually exclusive; students who worked in gap-year positions in clinical research may have continued to professional programs.

Thirty-eight students (40.4%) worked in clinical research (CR) during their gap year(s). Fifty-seven students (60.6%) enrolled in medical school, and 8 students (8.5%) enrolled in another health professional school (DDS, PA, etc.), either directly after the program or following gap-year experiences. Twelve students (12.7%) are currently working in (CR), and 11 students (11.7%) are working in another healthcare-related field (EMT, medical technician, etc.). We were unable to determine outcomes for five students following MBS graduation. Of the 2016–2023 MBS graduates for whom professional outcomes data were available ($N=337$), 207 students (61.4%) enrolled in medical school, and 48 students (14.2%) enrolled in another health professional school. Post-program employment data for MBS graduates were not collected.

Discussion

Course structure and resources

Clinical research competencies introduced in didactic sessions are reinforced through practical application to mentored research projects led by investigator mentors and supported by CRP mentors. This interprofessional approach exposes students to both the oversight responsibilities required in research and the collaboration and skills necessary for research conduct. The selective nurtures the student-mentor relationship through defined expectations and continuous communication and support.

Duke faculty and staff are strongly committed to the academic mission, and DOCR has leveraged these relationships, enabling effective implementation of the course and mentor recruitment and engagement. In addition to educating the next generation of researchers, mentors gain support for research tasks and a pathway for hiring new staff. As reported in our feedback surveys: “This mentorship worked out so well we decided to hire our mentee.” Mentoring students also promotes the development of leadership skills essential to CRP career advancement [19]. In turn, student feedback demonstrates the impact of the course and mentored research experience on competency development, as one student described: “The most useful aspect of the mentored experience was learning the basics on how clinical research works . . . I now feel a lot more confident in pursuing a future career in it.”

Productive student-mentor interactions help sustain the selective by demonstrating the benefit of student involvement to PI and CRP mentors and encouraging their participation. In addition, leveraging associations with staff and faculty contributors provides consistent, high-quality didactic sessions. Building and maintaining these relationships increases efficiency and minimizes the resources required for course conduct.

Demographics and student outcomes

While similar in some categories, racial/ethnic distribution among our students is comparatively more diverse than US MD-Granting Medical School Enrollment from 2023 to 2024: 43.9% White, 8.5% Black/African American, 24.9% Asian, 6.8% Hispanic/Latino, and 15.7% more than one race or unknown [20]. These data and the professional outcomes of our students suggest that the selective and MBS program contribute to the diversity of the healthcare and clinical research workforces while demonstrating students’ ongoing interest in clinical research and achievement of their professional goals. Of note, 13 students hired into gap-year positions were hired by their selective mentors, a testament to the effectiveness of the course in engaging students and mentors in mutually beneficial professional relationships.

Clinical research competency and course efficacy

Students gained the most confidence in competencies that align with our course objective to provide practical study conduct experiences. Increased confidence in research conduct and articulating IRB role and function reflect students’ typical day-to-day functions learned through interaction with mentor teams. Competencies showing smaller gains in confidence related to interpersonal and communications skills, as expected given the “soft skill” nature of the concepts and their relative complexity. Moreover, the retro-pre data suggest that students gained a deeper understanding of each competency through their didactic instruction and hands-on experience.

The perceived exposure data align with the intentional course emphasis on working and communicating as part of a team and typical activities for students (document review). Lower exposure to literature reviews is consistent with our prioritization of research conduct over contributing to publications.

Course feedback

Mentor and student feedback reflect overall satisfaction with the course. In response to student feedback regarding course expectations and activities, we developed a structured syllabus with grading rubrics and assignment guidelines and revised the didactic sessions to boost student interaction and engagement. We reduced redundancy and created synergy with the MBS program by encouraging students to use their mentored project for other MBS program presentations as appropriate. To address mentor challenges, we enhanced our onboarding process and materials, added required 1:1 meetings for mentors and students, and added more frequent check-ins with mentors by DOCR staff.

Several students sought experience in more varied research tasks. While we encourage mentors to involve students in diverse research activities, some repetition in assigned tasks is expected, given the limited time frame. Students' suggestions to lengthen the course were consistent with requests received from mentors to begin interactions with students earlier. While a two-semester course is not feasible with the MBS course load, we encourage students and mentors to meet and prepare in advance of the term.

Challenges and lessons learned

Despite our optimization process, we encountered specific challenges to the implementation and evaluation of the selective. The high-touch course design, which underpins its success, also limits scalability due to mentor availability and matching with student interests. Effectively managing student expectations, including requests to choose their own mentors and students' desire to achieve a research product (e.g., manuscript), necessitated thoughtful reinforcement of the course objectives and requirements.

The iterative course optimization process has confounded our ability to associate thematic shifts in feedback with course modifications. Changes in the research landscape during the COVID-19 pandemic also impacted our course and students' permitted activities, further complicating the analysis of student feedback over time as it relates to course evolution. Data analysis for this paper was confounded by the structure of data received from outside sources. Future implementation of similar programs should prioritize collecting uniform demographic standards.

Broadly, our course implementation has benefited from standardized goals and expectations for mentors and students, didactic sessions and activities that maximize student engagement, continuous communication and support for all participants, and mechanisms for measuring course outcomes and satisfaction. Feedback cycles have allowed us to optimize the mentor and student experience toward these goals.

Conclusion

The DOCR RI selective trains students in the conduct of clinical research through varied learning experiences designed to provide foundational knowledge applicable to students' future research endeavors. By constructing an innovative model that uses interprofessional mentorship in a structured multimodal adult

learning structure, we have provided a pathway for diverse learners to enter research professions, either exclusively in research careers or by including research in their career pathway into health professions. Our course enables a deeper understanding of research through collegial interactions and experiences that develop students' appreciation for research and potentially lay the groundwork for the inclusion of research in students' professional careers.

Supplementary material. The supplementary material for this article can be found at <https://doi.org/10.1017/cts.2025.42>

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Competing interests. The author(s) declare none.

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