Review Committee Members

Seth Blair, Professor of Zoology (UAPC Member, Committee Chair)
Lisa Forrest, Professor of Veterinary Medicine (Provost Appointee)
Caroline Alexander, Professor of Oncology (Graduate Faculty Executive Committee Appointee)
Lauren Trepanier, Professor of Veterinary Medicine (Consultant - Program Representative)

Background

The MS and PhD degrees in the Graduate Program in Clinical Investigation (GPCI) were established in 2008 and 2009, respectively, and are administered by the UW’s Institute for Clinical and Translational Research (ICTR). The following is the GPCI’s first, five year, review. The Committee’s discussions were based in large part on the GPCI’s 2015 Self-Study, as well as the 2008 review of the request to authorize the GPCI, and the final 2009 Program Authorization. This Committee’s report is organized to address the following review tasks identified in UW-Madison Provost Mangelsdorf's charge to the committee:

a. Determine whether the goals and objectives as stated in the original program proposal were met and evaluate if the program is meeting standards of quality that are expected based on the original proposal.

b. Confirm that the program is important to be delivered at UW-Madison and understand the program’s relationship to other programs at UW-Madison. Are other programs positively or negatively impacted? Are connections with other programs as planned in the original proposal developing as envisioned?

c. Determine if the resource implications of continuing the program are appropriate.

d. Offer the program faculty and/or the dean(s) any advice for program improvement and summarize any actions for follow-up or attention.

e. Provide an explicit recommendation as to whether the program should be continued.

Goals and objectives

The GPCI MS/PhD provides one of the several mechanisms through which the UW’s ICTR carries out its mission, to foster skills in clinical investigation and links to community medical practice. The GPCI has established a well-designed curriculum, combining common coursework and individualized MS and PhD thesis projects. The Program has had good success attracting and graduating students and fostering high-quality research projects, and has met its initial goals in terms of enrollment and degrees.

Relationship to other programs at UW-Madison

The Committee agreed that the GPCI, as currently designed, positively impacts the overarching goals of the ICTR, providing a valuable resource for health professionals and strengthening the University’s and the state’s standing in medicine and clinical research. The success of the ICTR-sponsored GPCI also improves the standing of the ICTR in competition with similar programs nationally, especially for support from the Clinical and Translational Service Award
(CTSA) program. The Committee found no negative impacts of the GPCI on other UW or state programs.

Program Resources

Current resources are sufficient to support the program as currently designed, and the Committee did not foresee any difficulties continuing with this level of support. The Committee does recommend some possible expansions of the GPCI below, and it is possible that some of these, especially increased recruitment of students nationally, might require additional mechanisms for student support from the GPCI or sponsoring faculty.

Program Improvement

1. Increase the Program’s National Standing. The Committee noted that most of the students served by the GPCI were Wisconsin-based health professionals, seeking improved training and accreditation in clinical research. Serving this clientele will continue to be quite important for the Program, the University and the state. However, the Committee felt the Program should do more to attract students from outside the Wisconsin health community. Such an expansion, building on the current strengths of the GPCI, would give it a national reputation, increase ICTR’s standing with CTSA, and increase the influx of skilled professionals to the University and the state. The Committee suggests the Program consider the following additions to foster this aim.

   A. Increase awareness of the Program. The Program is currently fairly low-profile, even within the local clinical community. The Program should increase publicity both locally and nationally, and develop systems to more actively recruit students. The Committee also suggests increasing awareness through the support of research presentations, both locally and at national meetings, by those currently or recently graduated from the program. This would also provide valuable experience for the students in the program.

   B. Create mechanisms for full-time PhD students. Many of the past and current program participants are part time students, often local health professionals. To create a national program, it will likely be necessary to create mechanisms more akin to those of other full-time PhD programs at the UW, such as lab/program rotations that allow new students to choose amongst a range of interests, and a codified system for support from the chosen lab and PhD supervisor.

2. Improve Program Assessment- While the Program has developed learning goals and some assessment mechanisms, it will be important going forward to assess explicit student outcomes, beyond enrollment and opinion polls, and assess impacts on minorities, first-generation university students and women.

Program Continuance

The Committee strongly supports continuation of the GPCI MS/PhD program.
May 20, 2015

Sarah C. Mangelsdorf, Ph.D.                      Wendy Crone, Ph.D.
Provost and                                      Professor and
Vice Chancellor for Academic Affairs             Interim Dean of the Graduate School
150 Bascom Hall                                  333 Bascom Hall
- campus -                                      - campus -

Sent Electronically

Re: Joint Review of the Graduate Program in Clinical Investigation

Dear Provost Mangelsdorf and Interim Dean Crone:

On behalf of the School of Medicine and Public Health, I wish to provide my personal endorsement of the self-study documentation provided by the Graduate Program in Clinical Investigation (GPCI). After discussion at the May 20, 2015 meeting of the SMPH Academic Planning Council, APC members have unanimously approved:

1. The self-study as an accurate representation of the program,
2. The self-study materials are adequate for the joint review, and
3. Recommended SMPH support for program continuation.

The APC was pleased to note that the GPCI has been remarkably successful in the five years since implementation, having already awarded 5 Ph.D. and 19 M.S. degrees.

I have attached the program’s self-study. Appendix materials as well as course syllabi, evaluations, and rosters are available online at: https://uwmadison.app.box.com/s/2x3nhfc0lrcslbmc3vx3gvwxyurvtvgv

Thank you for your consideration of this request. If you require additional information, please do not hesitate to contact my office. I look forward to reading the Joint Review Committee report.

Sincerely,

[Signature]

Robert N. Golden, M.D.
Robert Turell Professor in Medical Leadership
Dean, School of Medicine and Public Health
Vice Chancellor for Medical Affairs
University of Wisconsin-Madison
xc:
Marc Drezner, ICTR
Sally Wedde, ICTR
Rick Moss, School of Medicine and Public Health
Tracy Cabot, School of Medicine and Public Health
Daniel Kleinman, Graduate School
Marty Gustafson, Graduate School
Alan Joranlien, Graduate School
Jennifer Martin, Graduate School
Jocelyn Milner, Academic Planning and Institutional Research

Enclosures:
GPCI Self Study (May 2015)
ICTR Cover letter (May 2015)
May 20, 2015

To: Sarah Mangelsdorf, PhD, Provost
Jocelyn Milner, Associate Provost and Director, Academic Planning and Analysis

Subject: Joint Review of the Graduate Program in Clinical Investigation

We are delighted to write in response to the July 9, 2014, request from the Provost that the School of Medicine and Public Health and the Graduate Program in Clinical Investigation complete a five-year self-review of the graduate program (MS and PhD). As you may recall, the initial deadline of the review report, Feb. 1, 2015, was extended to June 1.

The self-study was completed over an 11-month period by the faculty and staff of the graduate program and reviewed closely by the Dean’s office. The process involved students, alumni, and faculty from all participating partners in the Institute for Clinical and Translational Research, the program’s administrative home. As you may know, these are the Schools of Medicine and Public Health, Nursing, Pharmacy, and Veterinary Medicine, and the College of Engineering, and Marshfield Clinic Research Foundation.

The MS in Clinical Investigation program received Board of Regents approval for Fall 2008; the PhD program for Fall 2009.

Thank you for your consideration of this self-review report. If you have questions, please contact either of us, or the graduate program administrator, Sally Wedde, at 262-3768 or sewedde@wisc.edu.

Richard L. Moss, PhD
Senior Associate Dean for
Basic Research, Biotechnology and
Graduate Studies,
School of Medicine and Public Health
Professor of Cell and Regenerative Biology

Marc Drezner, MD
Director, Graduate Program in
Clinical Investigation
Executive Director, UW Institute for
Clinical and Translational Research
Professor of Medicine
Self-Review
May 2015

Graduate Program in Clinical Investigation

Administered by the
Institute for Clinical and Translational Research
School of Medicine and Public Health

Marc K. Drezner, MD
Executive Director, Institute for Clinical and Translational Research
Acting Director, Research Education & Career Development Core
Senior Associate Dean, School of Medicine and Public Health
Professor of Medicine

Contact:
Sally Wedde, Administrator
Graduate Program in Clinical Investigation
sewedde@wisc.edu
262.3768
Five Year Self-Review, Graduate Program in Clinical Investigation (May 2015)

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See next page for information about accessing additional information about courses.
GPCI Syllabi, Evaluations, and Rosters are available online for Required Courses. Please request link from Sally Wedde, sewedde@wisc.edu, or Tracy Cabot, tlcabot@wisc.edu.

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<td>NonCr Activity</td>
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<td>NA (non-credit activity)</td>
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A. EXECUTIVE SUMMARY

As envisioned during the program development and approval steps, the strengths of the Graduate Program in Clinical Investigation are its multidisciplinary students, faculty, and curricular contributions from its participating academic partners, the Schools of Medicine and Public Health, Nursing, Pharmacy, and Veterinary Medicine, the College of Engineering, and the Marshfield Clinic Research Foundation. These complementary resources are deployed in training health professionals who earn the Clinical Investigation applied research master’s and doctoral degrees.

This document is the initial self-review of the PhD program, which admitted its first students in Fall 2009, and MS program, into which the first students matriculated a year earlier.

The mission of the GPCI is to train students to develop new technologies and therapeutic interventions using efficient and effective clinical trials to accelerate translation of clinical research discoveries to healthcare practices and communities in the State and throughout the Country. Resources used are appropriate. No resources–based adjustment of activities is planned.

The graduate program has exceeded its enrollment targets and more than met the time to degree expectations. In the program’s first five years, 5 professionals have earned the PhD, and in six years, 19 have earned the MS (the latest in May 2015).

Some 145 faculty in seven UW-Madison schools and colleges and the Marshfield Clinic have contributed to the program. They did so by serving as primary advisers or degree committee members for students, teaching required courses, or steering the program as members of the Executive Committee or its Admissions and Curriculum subcommittees.

The program is meeting or exceeding its initially stated quality standards. Data from graduate surveys show that 100% of our responding graduates would recommend the program to other health professionals. Evidence exists of student learning, improvement in careers post-graduation, and student maturity and ability shown by time-to-degree.

Though the graduate program enjoys rapport with graduates, current students, and new UW-Madison clinical and instructional hires, we do not offer funding for students, outside of a 6-slot NIH traineeship program open to PhD students and PhD Minor students. Our challenges are to attract more students with a more robust NIH funding mechanism; get more of those students who earn our PhD Minor to earn the PhD in Clinical Investigation instead; continue to recruit more full time students by developing dual degree programs; continue to recruit students funded by clinical fellowships and other existing programs; continue to encourage faculty to offer instructional content in non–traditional formats; and convince the University to reinstate financial incentives for our program to cater to non–traditional students by offering courses at 4 PM or later.

The Clinical and Translational Service Award (CTSA) program (catalyst for the existence of the GPCI) is moving the 62 CTSA–funded institutions into hubs of specialty activities. For the UW ICTR renewal proposal due in Dec. 2016, we will emphasize as one of our strengths the quality of MS and PhD
training that we provide as well as progressive improvements in training and recruiting multidisciplinary, patient-oriented researchers.

B. RESPONSE to REVIEW RECOMMENDATIONS: Not Applicable

C. PROGRAM OVERVIEW

Brief Description

The Graduate Program in Clinical Investigation (GPCI) offers an MS and PhD (and doctoral minor) for health professionals conducting patient-oriented (human or animal) research as part of multidisciplinary research teams. The goal of the training is to accelerate the movement of clinical research discoveries to healthcare practices and communities in Wisconsin and the United States. The graduate program was developed in response to the broadly recognized need, most notably by the National Institutes of Health, to stimulate clinical research and develop and promote clinical research training programs.

The students are unusual among UW graduate students because they enter the program with a terminal degree already (with exceptions) and they are seeking training to directly apply their work with patients.

The program has a unique leadership structure. Its administrative home, the Institute for Clinical and Translational Research (ICTR), is joined by academic partner Schools of Medicine and Public Health, Nursing, Pharmacy and Veterinary Medicine, and the College of Engineering to create, implement, and sustain the program. All partner schools are represented in the curriculum and are joined by the Marshfield Clinic on the faculty Executive Committee and subcommittees overseeing the program.

The curriculum draws from existing courses in the partner schools. Three courses and one non-credit activity were further developed for GPCI students. Coursework provides a solid foundation in research methods and analysis, including biostatistics, study design, and the ethical and responsible conduct of research, as well as interactions with faculty and students in other graduate programs. Working toward a doctoral dissertation or master’s thesis, students pursue patient-oriented clinical research.

Context

The GPCI provides physicians, clinical scientists, and other health care professionals with the knowledge and skills to conduct and translate basic science discoveries into clinical applications through patient (human or animal)-oriented research, or what is commonly known as "from bench to bedside." Research in the field of Clinical Investigation is classified on a continuum defined by the Institute of Medicine.

<table>
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<tr>
<th>Research Type</th>
<th>Definition</th>
<th>Keywords</th>
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<td>T0 Research</td>
<td>Basic biomedical research Identification of opportunities and approaches to health problems</td>
<td>DNA, proteins, cells, receptors, biomarkers</td>
<td>No human subjects interventions</td>
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</tbody>
</table>
identifies functional significance, mechanisms

T1 Research
Translation to humans
Seeks to move basic discovery into health application
First in humans, safety
Proof of concept
Phase 1 clinical trials
Highly controlled settings

T2 Research
Translation to patients
Health application to evidence-based practice guidelines
Efficacy
Algorithm testing
Phase 2 and 3 clinical trials
Yields knowledge about efficacy of interventions in optimal settings

T3 Research
Translation to practice
Practice guidelines to health practices
Delivering recommended and timely care to right patient
Comparative effectiveness, clinical outcomes research, post FDA approval
Development of guidelines, meta-analysis, systematic reviews

T4 Research
Translation to communities
Health practice to population health impact
Population level outcomes
Real world outcomes
Documents dissemination and implementation of practices and interventions

The value of the GPCI is evidenced by the patient-oriented research titles of our graduates' dissertations and theses (see Appendix, C1). The GPCI complements a graduate program in population health offered by the Department of Population Health Sciences. The two programs are distinguished by structure and research focus. Clinical Investigation emphasizes multidisciplinary team training, requiring fewer courses in epidemiology and outcomes research, and emphasizing bench to bedside patient-oriented research early in the T spectrum. In contrast, the population health program emphasizes clinical research later in the T spectrum and focuses on human populations and communities.

By offering cohesive instruction in applied research, the GPCI prepares students for careers in academia, industry, and research institutes, or with health or regulatory agencies. With few exceptions, applicants have a health professional degree (MD, DVM, PharmD, PhD, BSN, BSE, MPT, DPT). Full time and part-time enrollment are available to accommodate students who are working full time as, for example, clinical fellows or faculty.

The PhD and MS in Clinical Investigation are experiential, applied research degrees. What further sets the GPCI apart is (1) its applied research focus and extensive student services, due to its origin in the CTSA hub (ICTR), which provides comprehensive support to improve the biomedical workforce in a larger effort to bring solutions to patients more quickly; and (2) local (Wisconsin) recruiting, generally from ICTR partner schools/college and Marshfield.

The UW PhD in Clinical Investigation is one of six roughly comparable programs in the nation (Johns Hopkins, UC-Denver, UTX-San Antonio, University of Rochester, Tufts University, and Albert Einstein College of Medicine). No program is comparable in Wisconsin. The Responsible Conduct of Research Laboratory — regulatory oriented, experiential learning for PhD students — is innovative nationally. As initially expected, our program’s instructors are gradually developing more online course content.

The MS program attracts motivated health professionals who are willing to earn the degree part time while fulfilling clinical and research responsibilities. Nationally 32 other programs offer master’s degrees in clinical investigation, clinical research, or clinical and translational science, in addition to
five institutions that offer a variation. In two of the five, clinical research training is paired with epidemiology training. One offers an MD/MS. The other two combine clinical and translational sciences with a masters in public health (MPH). Compared to the UW GPCI current mandate of 30 credits (formerly 33 until Fall 2014), nine somewhat comparable programs require significantly more credits and one significantly fewer. We say “somewhat comparable” because not all Clinical and Translational Science Award institutions are on par with the size of the UW–Madison research enterprise.

The GPCI pays special attention to mentoring our students and trainees. We require trainees to complete extensive professional development questionnaires twice a year before each mentor meeting. Mentor meetings are attended by the student, major adviser, director of the graduate program and director of ICTR (currently the same person), and program administrator. A monthly grant and manuscript writing seminar is offered for trainees with opportunities for peer and faculty mentor critiques.

Students and trainees are required to develop and share annual Individual Development Plans with their faculty mentors; all have done so ahead of deadlines because career development is inherent in seeking these degrees. In addition to the GPCI coursework, students have access to many other career development opportunities offered by the ICTR Research Education and Career Development core. These offerings include research mentor training, facilitator training (faculty get trained to train other mentors), grant and manuscript writing workshops, and advanced clinical and translational topics such as clinical research study design. Occasionally, panel presentations offer the opportunity for students and faculty to participate. For example, during a recent session at the Advanced Short Course in Clinical and Translational Research, current and former GPCI students joined faculty mentors to lead a discussion about negotiating effective mentoring relationships. GPCI students also have access to other ICTR resources such as the services of a scientific editor and mock reviews of grant proposals.

**Graduate Program within a National Standard-Setting Institute.** A 1998 NIH Directors report affirmed a need to stimulate clinical research to more rapidly bring breakthroughs into clinics and more aggressively advance treatment options. Since 1999, the NIH has invested in clinical research through various career development award mechanisms to support junior investigators (K08, K23, K24 awards). Between 1999 and 2003, 59 academic institutions, including UW–Madison, were granted about $1 million each (direct costs) to develop and implement clinical research training programs (K30 awards).

As part of the 2005 Roadmap for Re-engineering the Clinical Research Enterprise, NIH combined several funding programs into the NCRR U54 Clinical and Translation Science Award (CTSA). In 2007, 12 institutions received CTSA awards to create cost-effective infrastructures that provide academic homes for clinical investigators. Of the 12 awarded in 2007, UW–Madison was the only CTSA awarded on its first submission.

Today UW ICTR is a leader among 62 CTSA sites nationwide. The ICTR External Advisory Committee commented after its site visit in November 2014 that UW ICTR “sets the standard” for CTSA programs.
This graduate program’s academic home is an institute that provides trans-disciplinary services to clinical and translational researchers [https://ictr.wisc.edu/], including career development training, to bring clinician-scientists through the T0–T4 process, ultimately to bring solutions to patients faster. This approach is beneficial to Clinical Investigation MS and PhD students as learners and as models for other researchers. The nature of being a Clinical Investigation graduate student is to plan and communicate with trans-disciplinary research partners at a level nearly unparalleled on campus.

From 2002 to 2009, 11 students completed the Capstone Certificate in the Fundamentals of Clinical Research. The certificate program was developed by the Department of Biostatistics in 2001 in response to a challenge from Chancellor David Ward to offer additional training to researchers in the community who are not engaged in a formal graduate program. Development of the Capstone Certificate set the stage for what would later become the GPCI. A more extensive training program, the Clinical Investigator Preparatory Program (CIPP), was developed as a result of the SMPH receiving NIH K30 funding in 2005. The CIPP became mandatory for MDs and other professionals in the NIH-funded TEAM scholars program. Nineteen scholars received CIPP certification from 2007 through 2009. The content of the CIPP was folded into the new MS in Clinical Investigation, approved in Fall 2008 for

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**Student Trailblazers for Creation of the GPCI**

In Fall 2000, Michelle Roth–Clíne and Kat Sullivan Dillie entered the UW Medical School and also declared PhDs in clinical investigation, by special committee. With the help of the Biostatistics Department Chair Dave DeMets, PhD, and others, they pieced together existing courses that would help them become clinical investigators, *though no Clinical Investigation graduate program existed yet.*

Michelle simultaneously earned her PhD by taking up to 25 credits per semester, for 16 semesters, including summers. She was mentored by Dr. Norm Fost. In the last full year, bookended by two summers, she enrolled in 990 research, law courses, and completed her medical clerkship while writing her dissertation, titled, “Data and safety monitoring in clinical trials: An examination of selected ethical, legal and policy dilemmas.” She earned her PhD in August 2006 and MD in Spring 2009. She now works for the Food and Drug Administration as a pediatric ethicist in the Office of Pediatric Therapeutics.

Kat took seven semesters of medical school coursework, including a summer statistics practicum, and took graduate courses that helped shape the current GPCI, including Ethical and Regulatory Issues in Clinical Investigation, Statistical Methods for Bioscience I and II, Intro to Epidemiology, and other courses in quantitative tools and methods. She also took microeconomics for public policy analysis, her PhD Minor. Kat took Epidemiology Methods and spent a year and two summers enrolled in 990 Research to write her dissertation. She defended it the same semester she completed two clerkships. Mentored by Dr. DeMets, Kat earned the doctorate by special graduate committee in Clinical Investigation with a Minor in Public Affairs in December 2006 and the MD in Spring 2008. She is now a staff physician and group research director of a Medical Group Practice (ERMED SC) in Milwaukee. She has published nine peer-reviewed papers since 2005 — three as first author.

Drs. Roth–Klein and Dillie are examples of former students who helped blaze the trail for creation of the GPCI. A current GPCI student, Kimberly Shoenbill, is earning the PhD in Clinical Investigation with a special graduate degree committee, to accommodate her interest in clinical informatics — the use of medical information collected from patients (and electronic health records). Like Kat, Michelle, and other GPCI students, Kimberly likely will have a direct effect on health care in the future.
administration through ICTR, and the CIPP was discontinued. The PhD Minor in Clinical Investigation also was approved. A PhD program in Clinical Investigation was approved for Fall 2009.

The GPCI PhD program competes with UW–Madison’s other biomedical graduate programs for full time students who could be funded by our NIH TL1 pre–doctoral training grant (the CTSA version of T32). On this campus, however, the Clinical Investigation PhD is the only applied clinical and translational research doctorate.

**Faculty**

Per its original plan, the faculty Executive Committee conducted a review of program faculty (completed in January 2015). The review was performed as two requests of faculty: Gathering information about student mentoring, teaching, and serving on program governing committees, and confirming faculty funding and research.

Some 145 faculty have participated in launching and implementing the program to date. This includes 47 faculty who currently mentor students as primary advisers or degree committee members. A detailed spreadsheet of the faculty review results is in C2. C3 contains a list of the 47 active advisers, and the criteria for major faculty advisers in the program.

Five faculty have conducted 4 or all 5 major program activities (Chen, DeMets, Kim, Mendonça, Sorkness). Seven have participated in 3 activities (Asthana, Barrett, Gangnon, Gern, Jarjour, Trentham Dietz, Trepanier). Some 22 faculty teach required (or formerly required) courses. Five of these faculty members teach or have taught more than one required course (DeMets, Kim, Mendonça, Sorkness, Thorne). Many of these faculty members, and additional faculty, have been involved in other ICTR endeavors, such as teaching non–credit courses, or mentoring pre–doctoral or postdoctoral trainees.

Two members of GPCI and ICTR partner Marshfield Clinic actively serve as core faculty, but are limited by UW–Madison to zero dollar University appointments and advisory votes on GPCI governance committees. Nonetheless, a Marshfield Clinic scientist (Greenlee) is a current invaluable member of the Executive and Admissions committees. Marshfield is a critical and equivalent partner to the on–campus academic partners in research education efforts provided with the ICTR framework. Specific Marshfield facilities and initiatives are described in C4.

Marshfield Clinic leaders state that about 30 researchers have benefitted from the partnership with ICTR. They consider research and education integral to the Clinic’s culture, sustained growth and quality of care since 1916, and further state that the level of collaboration (~14 projects) is unprecedented and likely to affect Marshfield’s clinical and translational research for decades [Source: Humberto Vidaillet, Director, Marshfield Clinic Research Foundation, research forum presentation Sept. 14, 2011]

**Staff**

A brief biography of persons who operate the GPCI is in C5.

**Budget**
UW ICTR receives funding from multiple sources that include the NIH Clinical and Translational Science Award, UW Hospital & Clinics, UW Medical Foundation and the Chancellor’s Office. ICTR resources dedicated to GPCI are detailed below and amount to a total annual budget of $189,649. ICTR provides fiscal support for administrative and student services, as well as funding for nine GPCI required courses through Teaching Assistant stipends and instructor compensation. As detailed in this report’s description of five–year changes for each course, ICTR is funding instructor and TAs to help ensure space in courses for GPCI students. This solution is working well.

### GPCI Administrative Expenses

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<th>Salary Expense</th>
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- NSG 705 Seminar in Interdisciplinary Clinical Research Evidence
- MHB 545 Ethical and Regulatory Issues in Clinical Investigation
- BMI 541 Introduction to Biostatistics
- PHS 797 Introduction to Epidemiology
- BMI 542 Introduction to Clinical Trials I
- BMI 544 Introduction to Clinical Trials II
- FMD 701 Perspectives in Multidisciplinary, Clinical and Translational Research
- BMI 773 Clinical Research Informatics
- CSD 900 Research Career Development Seminar on Grant Writing

### Related Student and Course Resources

- Faculty Instructors: Academic Home Departments
- Teaching Assistants: Academic Home Departments/ICTR
- GPCI Committee Members: No compensation
- GPCI Faculty Advisers: No compensation
- HSLC Video Recording: No compensation

### D. EDUCATIONAL PROGRAM and STUDENTS

#### Program Structure and Governance

The graduate program admits MS and PhD applicants for Fall only. (It accepts PhD Minor, certificate, and program transfer students year–round.) It has no subspecialties/tracks. It is the only graduate program housed in the ICTR, though ICTR also has two certificate programs. (The graduate program administrator runs the Certificate Program in the Fundamentals of Clinical Research and helps an
outreach specialist in the School of Nursing run the Certificate in Clinical and Community Outcomes Research. Each certificate addresses a need based on the student’s phase of research on the translational spectrum previously described.)

Students secure a faculty primary adviser before applying, through whom they also secure funding, though having these things does not guarantee admission. It is not a direct admit program. The graduate program does not offer rotations or funding to students, except for the small (6-seat) career development and training award (TL1) limited by the NIH to full time PhD students and PhD Minors.

Because the PhD and MS in Clinical Investigation are applied research degrees, a relatively large percentage of students in the GPCI (63% in Fall 2014) start as Special Students. This mode of entry affords them the opportunity to try out a class or two before deciding whether to commit to earning the formal degree. This pipeline was not conceived by the program, but is proving popular to the professionals attracted to this field, and successful for recruiting students who complete the degrees. Those students who have chosen to take a course at a time, and who determine that coursework fits into their clinical and health professional workloads, have then proceeded to earn the MS or PhD in Clinical Investigation. When the academic demands did not fit with other professional demands, students have tended to leave the program (details in Degree Completion Patterns, page 23).

The program has a unique governance structure, in which all partner schools and colleges and Marshfield Clinic (non-voting) make program decisions. The chairs of the subcommittees on Curriculum, and Admissions, automatically are members of the Executive Committee. The Executive Committee and Admissions Subcommittee have a Marshfield representative (non-voting). The Curriculum Subcommittee includes two students (non-voting).

All program decisions, including changes in the curriculum, are approved by a subcommittee, Executive Committee, SMPH Academic Planning Council, four other academic partners school/college APCs, followed by notification to the Graduate School (only if the change is outside GFEC guidelines, otherwise GFEC vote), the Provost, and the University Academic Planning Council.

Delays in implementing curriculum changes occur routinely after the program approves them because of the charter requirement, peculiar to this graduate program, that all five Academic Planning Councils approve changes.

The Executive Committee, currently with nine voting members, is the 2012 successor to the Faculty Governance Committee, which had 23 members when the GPCI was established. The larger committee participation and input was beneficial as the program was forming. As the program matured, the decision was made to streamline committee structure. Two subcommittees were created (Admissions and Recruiting, Curriculum). As needed, the Executive Committee appoints ad hoc committees which convene and disband once objectives are met (example: the RCR Courses Options Committee, no longer active).

Membership in GPCI committees is listed in Appendix, D1. The benefit of the multi-school/college governance structure is that program questions are discussed and decisions made by faculty from
across disciplines who can share multiple perspectives. The multidisciplinary team based approach to governance mirrors the training of GPCI students to function in teams that transcend disciplines in order to achieve research and societal goals.

**PhD and MS Student Curriculum, Defense, and Career Planning Requirements**

Eight required courses are in common for Clinical Investigation PhD and MS students. Four additional requirements are in effect for PhD students. One additional course is mandated for MS students. (Research and Minor/Electives are excluded from the narrative below; the full list of requirements is in Appendix, D2.) The ICTR, as a non-department, does not “own” courses; they reside in multiple departments and schools determined by the academic home of each instructor.

The 8 courses in common are: Introductory Biostatistics (BMI 541/699), Intermediate Statistics (applicable to the student’s research); Introduction to Clinical Trials I (BMI 542) and II (BMI 544); Perspectives in Multidisciplinary Clinical and Translational Research (FMD 701); Introduction to Epidemiology (PHS 797); Seminar in Interdisciplinary Clinical Research Evidence (NSG 705); and Responsible Conduct of Research (6 options).

Four additional requirements of PhD students are two Advanced Statistics courses (applicable to the student’s research), a non-credit RCR Laboratory (described below); a course in Clinical Research and Medical Informatics (BMI 773, formerly BMI 826 and BMI 699); and a Research Career Development Seminar on Grant Writing (CSD 900).

The one additional course requirement for MS students is a seminar on Patient-Oriented Research Presentation Skills (BMI 699).

Defense of a thesis (MS) or dissertation (PhD) before the faculty degree committee is required. In addition, PhD students finished with coursework must pass one preliminary examination – an oral defense of a written research proposal – in order to become dissertators.

**Defense Requirements for Clinical Investigation Masters or Doctoral Degree**

<table>
<thead>
<tr>
<th>MS Thesis Defense</th>
<th>PhD Dissertation Defense</th>
</tr>
</thead>
<tbody>
<tr>
<td>Format: Technical Report or Traditional Thesis</td>
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</tr>
<tr>
<td>Not a literature review</td>
<td></td>
</tr>
<tr>
<td>Suitable for national publication</td>
<td></td>
</tr>
<tr>
<td>Treats significant problem in sufficient depth to contribute to clinical or translational knowledge</td>
<td></td>
</tr>
<tr>
<td>Includes title, abstract, introduction, methods, results, discussion</td>
<td></td>
</tr>
<tr>
<td>Format: Traditional or Three-Research Papers</td>
<td></td>
</tr>
<tr>
<td>Material is original contribution to field</td>
<td></td>
</tr>
<tr>
<td>Suitable for national publication conforming to publishable standard</td>
<td></td>
</tr>
<tr>
<td>If traditional format, exploration of single topic from which papers may be drawn later</td>
<td></td>
</tr>
<tr>
<td>If research paper format, 2 of the papers must present new empirical analyses</td>
<td></td>
</tr>
<tr>
<td>Includes title page, abstract, acknowledgements, table of contents, intro, (background), lit review, aims, methods, (results or manuscripts), conclusions, bibliography, appendices</td>
<td></td>
</tr>
</tbody>
</table>
The student schedules the PhD dissertation defense or MS thesis defense meeting with the degree committee directly and informs the program of the date, time and place at least 3 weeks prior.

Because GPCI students are working health professionals, the program provides flexibility by accepting prior coursework to the extent feasible. Details about the policy are provided to the Graduate School in the “Minimum Degree Requirements and Satisfactory Progress Chart” and posted in the Student Handbook (D3).

Some 58 percent of GPCI students (current and graduates) have participated in the ICTR non-credit career development program. Training topics have included working with peer-review journal editors; obtaining an NIH Research award; obtaining an NIH individual fellowship award; working with one’s mentors effectively; recruiting and retaining human subjects for research; and working as a team scientist. Seven graduates and current students have presented or served as panelists in ICTR non-credit short courses and workshops.

The GPCI requires its students to create and discuss with their mentors an Individual Development Plan (IDP). The two August 2014 orientation events for new students and trainees included training focused on IDPs. All participants brainstormed solutions to issues identified by students as they began developing a career development plan. Before the orientation, the GPCI program directed students to create an IDP using myIDP (http://myidp.sciencecareers.org) established by the American Association for Advancing Science. Clinical Investigation students use the UW Graduate School site as well as the program office for IDP and career development resources and training.

Breadth in Training

Through an infrastructure of team research experience and diversified coursework, the program provides clinician scientists exposure to, and training with, faculty from a wide variety of scientific disciplines (e.g. biostatistics and medical informatics, biomedical engineering, oncology, nursing, pharmacy, and veterinary sciences) to prepare them to direct patient-oriented research teams, comprised of scientists from inside and outside their own scientific disciplines. The GPCI is inherently interdisciplinary. At the time students request the Preliminary Exam Warrant, they are required to provide the program office with two paragraphs summarizing their interdisciplinary coursework experience and the heterogeneous and diverse research teams with which they have interacted. Alternatively, students may wish to complete a PhD Minor and submit a Completion of Minor form at the time they request the Preliminary Exam Warrant. This policy is in effect starting Fall 2014 with Graduate School approval.

Prior to Fall 2014, GPCI doctoral students were required to earn a 10-credit Minor, and master’s students 6 elective credits. Total required credits for the PhD had been 61–62; the MS, 34–35, depending on whether a 1– or 2-credit ethics course was chosen. The program has received many comments, particularly from MSTP students (desirable applicants because they are eligible for NIH training funds) that the number of credits required was too high. Most of them have chosen a different PhD program in the middle of their UW physician training. D4 compares the current total credits to selected other PhD degrees at UW–Madison.
The effect of removing the Minor/Elective requirement is to reduce total PhD credits by 10 (1–2 semesters), and MS by 4. The totals depend on which biostatistics and ethics courses are taken.

For most of the reporting period, elective courses were required. Several students in Clinical Investigation have voluntarily taken more courses than required, to fill gaps in the knowledge they need for their careers, in consultation with their primary faculty advisers and the program administrator.

**Typical Course Plan for MS in Clinical Investigation** (also an example of a part time plan)

<table>
<thead>
<tr>
<th>Fall 1 (7)</th>
<th>Spring 1 (6)</th>
<th>Summer 1 (2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>PHS 797 Intro to Epidemiology (3)</td>
<td>BMI 542 Intro to Clinical Trials I (3)</td>
<td>Med 705 Clinical Res’ch Evidence (2)</td>
</tr>
<tr>
<td>BMI 541 Intro to Biostatistics (3)</td>
<td>Path 404 Principles Human Disease (3 elec)</td>
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</tr>
<tr>
<td>MedHist 545 Ethics and Regulat Issues (1)</td>
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<table>
<thead>
<tr>
<th>Fall 2 (7)</th>
<th>Spring 2 (4)</th>
<th>Summer 2 (2)</th>
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</thead>
<tbody>
<tr>
<td>BMI 544 Intro to Clinical Trials II (3)</td>
<td>BMI 773 Intermed statistics (3)</td>
<td>Med 990 Research (1)</td>
</tr>
<tr>
<td>Med 701 Survey of Clinical Investig (3)</td>
<td>Med 990 Research (1)</td>
<td></td>
</tr>
<tr>
<td>BMI 699 Res Presentn Skills (1)</td>
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<th>Fall 3 (5)</th>
<th>Spring 3 (2)</th>
<th>TOTALS</th>
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<td>Med 990 Research (2)</td>
<td>Med 990 Research (2)</td>
<td>35 credits: 22 major, 6 minor, 7 research</td>
</tr>
<tr>
<td>Stats 327 Using R Language (3 elec)</td>
<td>Defend Thesis</td>
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For the PhD student, a representative course plan with a Minor *during this reporting period* includes 34 credits through required courses; 10 Minor credits (in Population Health Sciences, in this case); and 18 Research credits, for a total of 62 credits.

**Typical Course Plan for PhD in Clinical Investigation** (also an example of a full time plan)

<table>
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<th>Spring 1 (8)</th>
<th>Summer 1 (3)</th>
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<tr>
<td>PHS 797 Intro Epi (3)</td>
<td>BMI 542 Intro Clin Trials I (3)</td>
<td>Med 705 Clin Res Evidence (2)</td>
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<tr>
<td>BMI 541 Intro Biostats (3)</td>
<td>Path 500 Res Ethics (2)</td>
<td>Med 990 Research (1)</td>
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<tr>
<td>PHS 651 Adv Regress Methods (3)</td>
<td>PHS 652 Missing Data (3)</td>
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<th>Fall 2 (8)</th>
<th>Spring 2 (9)</th>
<th>Summer 2 (3)</th>
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<tbody>
<tr>
<td>BMI 544 Intro to Clinical Trials II (3)</td>
<td>BMI 773 Intro to Biomedical informatics (3)</td>
<td>Med 990 Res (3)</td>
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<tr>
<td>Med 701 Survey of Clinical Investigation (3)</td>
<td>PHS 850 Applied Regress Analysis (3)</td>
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<td>Non-credit RCR laboratory (0)</td>
<td>PHS 796 Health Sci Research (3 minor)</td>
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<tr>
<td>Med 990 Research (2)</td>
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<th>Summer 3 through Defense</th>
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<td>CSD 900 Grant Writing (3)</td>
<td>Med 990 Res (3/semester)</td>
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<tr>
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<tr>
<td>PHS 640 Fdns Global Health (3 minor)</td>
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<tr>
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<th>Summer 3 through Defense</th>
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<tbody>
<tr>
<td>Med 990 Res (3/semester)</td>
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Because the field of clinical investigation is driven by a team science approach, the GPCI learning goals reflect this. The GPCI provides opportunities for education in higher level thinking, defined as “project-based and applied learning. It can focus on higher–order skills — like how to distinguish good information from bad, how to apply information to new arenas, how to solve problems, how to communicate and collaborate with others different from ourselves, and how to discover new information through applied and basic research.” [Source: Aaron Brower, UW–Madison vice provost for teaching and learning https://tle.wisc.edu/tleblogs/ambrower].
The GPCI’s first four **Learning Goals** overlap for masters and doctoral students:

- Determine when it is and is not appropriate to use a multidisciplinary patient-oriented research design to investigate a therapeutic problem;
- Conceptualize and design multidisciplinary patient-oriented research protocols;
- Execute multidisciplinary therapeutic intervention studies; and
- Interpret and report research findings using the expertise of collaborators in multiple disciplines.

Masters students, further, are expected to learn to:

- Contribute to the leadership of programs that integrate clinical and translational science across multiple departments, schools and colleges, clinical and research institutes, and healthcare delivery organizations; and
- Translate research from the laboratory to the clinic through technological innovations, such as drug therapies, medical devices or biological materials (“bench to bedside”), as an active participant in a multidisciplinary clinical research team.

PhD students are expected to lead such teams, per these objectives:

- Disseminate knowledge through teaching and mentoring students/trainees;
- Lead programs that integrate clinical and translational science across multiple departments, schools and colleges, clinical and research institutes, and healthcare delivery organizations; and
- Translate research from the laboratory to the clinic through technological innovations, such as drug therapies, medical devices or biological materials (“bench to bedside”).

**Annual and Continuous Assessment**

The graduate program is assessed through at least 10 mechanisms, many of which were delineated at program approval.

- On-site review by the ICTR External Advisory Committee (annually)
- On-site review by the NCATS which administers the CTSAs (periodically)
- Review of program faculty research, funding, and mentoring fit, by the Executive Committee (every four years)
- Alumni surveys (every five years)
- Student feedback provided to program administrator during student services meetings (daily)
- Discussions and troubleshooting by the five-school/college + Marshfield Clinic faculty Executive Committee and its Admissions and Curriculum subcommittees (continuously and quarterly)
- Discussion between faculty advisors and the program administrator about student progress and the quality of three student work products: the research proposal (preliminary exam) and MS thesis or PhD dissertation defense (periodically)
- Monitoring of student enrollment and progress by the program administrator (semesterly) and faculty governing committees (quarterly)
- Course evaluations (annually)
• Conversations with alumni (daily)
• 5-Year Self-Review required by the UW Graduate School

Each new student creates a degree completion plan, in person with the program administrator. The primary adviser is invited to participate. The administrator continually monitors student progress and reports on progress, issues and potential problems to the Curriculum Subcommittee or Executive Committee. The Executive Committee annually reviews the curriculum. An example of one such review is in D5. Student course evaluations of required courses each semester are requested of instructors by the program routinely. These assessments inform future program planning and curricular improvements.

Our initial statements are still true that the purpose of the program is to provide investigators the appropriate knowledge and skills to perform patient-oriented research, and that “direct evidence of program success comes from reviewing the extent to which alumni achieve this broad goal.” Upon program approval in 2008, we envisioned that some effectiveness “(v)ariables [would] include a review of publication, grant awards, national and local presentation records, innovations, policies, procedures, job title, position, industry, patents, spinoff companies, and the emergence of new therapeutic treatments.”

In accordance with original plans, five years into the PhD program in Fall 2014, the program conducted a comprehensive survey of 5 PhD and 17 MS graduates, focusing on alumni perceptions about the value of the program to their research careers. The survey questions are shown in D6. Twenty-one of 22 MS and PhD graduates responded in detail and provided updated CVs.

Summary of Course Evaluations and Assessment Process

Continuous improvement of GPCI courses is an important element of the program and involves many people, including: Faculty advisers, Executive, and Curriculum committees, students, the GPCI program director and administrator, course instructors and Teaching Assistants. The GPCI curriculum was created by the Faculty Governance Committee — with participation from all partner schools/colleges and Marshfield. The 23 members approached the challenge knowing that GPCI students would need to integrate information from several disciplines to address clinical and translational research questions.

The Curriculum Subcommittee considers all curricular issues affecting the GPCI. Per its “charter” from the Faculty Governance Committee, the Curriculum Subcommittee considers all curricular issues and regularly reviews and recommends to the larger committee any changes in courses, learning objectives, requirements, and new courses. The Subcommittee decides whether student-proposed specific courses are fully equivalent to GPCI required courses (course waiver requests), reporting for approval to the full committee. The Curriculum Subcommittee is comprised of clinical and translational researchers — several of whom teach required courses — and is chaired by the Biostatistics and Medical Informatics representative. Members have three-year terms, with two terms ending each year. Reappointment is possible after a year off. Generally planned turnover has resulted in the Curriculum Subcommittee
selecting five new members and three non-voting members (two students and the program director). Members are listed in D1.

Curricular Changes Based on Assessment

The many established assessment mechanisms along with the faculty governance structure as described above has resulted in several curricular and related changes over the history of the GPCI (six years MS/five years PhD). The changes, course by course, are described below (see D7 for summary of changes).

Ethics Course Options (Fall and Spring, 1–2 cr). The original RCR course options for GPCI students were Med Hist 545, Nursing 802, and Vet Surg Sci 812. Pharm Sci 800 was added in Fall 2011. Changes in RCR courses in this reporting period: Grades were provided instead of credit/no credit. One credit (from 1) was added to Pharm Sci 800 by the School of Pharmacy (the course is required for PhD students in Pharmaceutical Sciences), based on student feedback. A half-hour was added to the course time. Oncol 675 was added to the GPCI curriculum as an ethics option in Spring 2011, and Ob/Gyn 955 in Fall 2013. The addition of three new options gives students more scheduling flexibility. All 6 ethics options include the elements of RCR training required by the NIH.

RCR Laboratory (Fall, 0 cr). The original research ethics/RCR requirement for PhD students in Clinical investigation included a 1–2 credit lecture in the ethical conduct of research and 1 credit of a RCR laboratory. Several lecture courses contained extensive regulatory content, but none included actually participating in an IRB meeting. The new RCR laboratory offers students the experience of preparing for and participating in IRB meetings and to enhance the regulatory content that PhD students would receive on their way to becoming PIs.

Rather than establish an entire course for this single activity, PhD students are required to take an ethics lecture course (one of the 6 options) which contain substantial regulatory content and participate in a non-credit faculty-supervised activity of preparing for and participating in an IRB meeting with an IRB committee member. This reduced the PhD total requirement by 1 credit starting Fall 2013. Student participation includes orientation before the regulatory committee meeting, debriefing after the meeting, prior Protection of Human Research Subjects and HIPAA training, a confidentiality agreement, and a vote by the committee to allow the students as guests.

The chair of the Executive Committee, chair of the Curriculum Subcommittee, and program administrator summarized student evaluations for each required course. These are provided in D8.

The following is a description of each additional required course, its instructors, delivery methods, any problems identified, and solutions reached or underway in the five-year reporting period. For each relevant course, the GPCI MS and PhD head count is shown along with total students enrolled. Other GPCI- associated students are not counted, such as those earning a Certificate or a Minor in Clinical Investigation.

Family Medicine 701 Perspectives in Multidisciplinary Clinical and Translational Research (3 credits, Fall). One instructor, one TA, guest lecturers, lectures (available post-class online), discussion. Course developed for GPCI
students. The course provides an overview (“survey”) of the field of clinical investigation. Executing the course’s original description, to introduce students “to scientific methods used for clinical translational research” proved too much to tackle in one course, with three instructors, guest lecturers, several required readings, optional readings, and a requirement to write an original manuscript or proposal for critique. BMI 542 and 544 eventually offered similar content.

After Fall 2009, the GPCI Faculty Governance Committee requested streamlining the course and eliminating the large writing requirement. The course returned in Spring 2011 and 2012, when the new Curriculum Subcommittee oversaw further honing of course content and format. Enrollment was lower this past year due to a smaller number of GPCI applications in 2012.

The GPCI administrator is working with the Department of Family Medicine to change it to a 2-credit course, per the GPCI Curriculum Committee. If the approving bodies OK this change, then an MS student might take 1 more research credit, depending on which biostatistics (1 or 3 credits) and ethics (1 to 2 credits) course they choose.

**Biostatistics and Medical Informatics 541 Introduction to Biostatistics** (3 cr, Fall), and **BMI 699** (1 cr, Fall). One instructor, one TA. Lecture, discussion. A one credit version of this course was developed at the request of the GPCI in response to frequent requests from students who had taken Statistics, outside of the GPCI, for exemption from repeat content (example: earned Pharmaceutical Sciences BS and took Pharmacy 301). The course instructor attended a GPCI Curriculum Subcommittee meeting and agreed to develop a 1-credit version of the course for Fall 2014.

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<th>FMED 701</th>
<th>2009</th>
<th>2010</th>
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<th>2012</th>
<th>2013</th>
<th>2014</th>
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<td>Instructors</td>
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<tr>
<td>GPCI MS and PhD Students</td>
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<th>2011</th>
<th>2012</th>
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<tbody>
<tr>
<td>Instructors</td>
<td>Adin-Cristian Andrei</td>
<td>Ismor Fischer</td>
<td>Ismor Fischer</td>
<td>Adin-Cristian Andrei</td>
<td>Mary Lindstrom</td>
<td>Mary Lindstrom</td>
<td>Mary Lindstrom</td>
<td>Mary Lindstrom</td>
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<tr>
<td>GPCI MS and PhD Students</td>
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<td>10</td>
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<td>7</td>
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<td>Total Students</td>
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<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Instructors</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>GPCI MS and PhD Students</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>0</td>
</tr>
<tr>
<td>Total Students</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>3</td>
</tr>
</tbody>
</table>
and exams. The instructor talks with each prospective student to determine appropriate credit level before registration. Three GPCI-associated students took the 1-credit class in Fall 2014.

Enrollment is shown dating back to 2007 because our graduates took the course pre-GPCI.

**BMI 542 Introduction to Clinical Trials I** (3 cr, Spring 1st 8 weeks). Instructor, TA. Course further developed for GPCI students. The course provides instruction in the planning, conduct, analysis, and reporting of randomized, controlled clinical trials, through didactic lectures, weekly assignments, critique of a published randomized clinical trial (in sections), and development of a clinical trial protocol at the end of the course. Course evaluations reveal that students consider this course highly relevant and appreciate the expertise of the professor.

Enrollment is provided back to 2007 because our graduates took the course pre-GPCI.

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Instructors</strong></td>
<td>David DeMets</td>
<td>Kyungmann Kim</td>
<td>Kyungmann Kim</td>
<td>Kyungmann Kim</td>
<td>Sheng Zhang</td>
<td>Kyungmann Kim</td>
<td>Kyungmann Kim</td>
<td>Jim Anderson</td>
</tr>
<tr>
<td><strong>GPCI MS and PhD Students</strong></td>
<td>1</td>
<td>1</td>
<td>3</td>
<td>11</td>
<td>8</td>
<td>6</td>
<td>6</td>
<td>1</td>
</tr>
<tr>
<td><strong>Total Students</strong></td>
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<td>24</td>
<td>22</td>
<td>29</td>
<td>19</td>
<td>19</td>
<td>29</td>
<td>21</td>
</tr>
</tbody>
</table>

**BMI 544 Introduction to Clinical Trials II** (3 cr, Fall). Instructor, TA. The course was developed for eventual GPCI students. This course provides practical experience in clinical trial research; specifically, the design, implementation, and conduct of clinical trials. Topics include regulatory requirements for clinical trials; subject recruitment strategies; data collection strategies; data quality and management; budget development and justification; federal, institutional, and sponsor-defined requirements; establishment of research infrastructures for safety and success; and investigator responsibilities in Phase I–IV trials. Development of data collection and data management systems and a budget for the protocol developed in BMI 542 (or an alternative protocol) are required components of this course. Three student class presentations are also required. The class currently features 17 guest presenters. Enrollment is tallied back to 2007 because our graduates took the course pre-GPCI.

<table>
<thead>
<tr>
<th>BMI 544</th>
<th>2007</th>
<th>2008</th>
<th>2009</th>
<th>2010</th>
<th>2011</th>
<th>2012</th>
<th>2013</th>
<th>2014</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Instructors</strong></td>
<td>Marian Fisher, Christine Sorkness</td>
<td>NA</td>
<td>Christine Sorkness</td>
<td>Christine Sorkness</td>
<td>Christine Sorkness</td>
<td>Christine Sorkness</td>
<td>Christine Sorkness</td>
<td>Christine Sorkness</td>
</tr>
<tr>
<td><strong>GPCI MS and PhD Students</strong></td>
<td>1</td>
<td>NA</td>
<td>3</td>
<td>10</td>
<td>8</td>
<td>5</td>
<td>6</td>
<td>3</td>
</tr>
<tr>
<td><strong>Total Students</strong></td>
<td>4</td>
<td>NA</td>
<td>5</td>
<td>14</td>
<td>11</td>
<td>10</td>
<td>8</td>
<td>9</td>
</tr>
</tbody>
</table>

**BMI 546 Practicum in Clinical Trial Data Analysis and Interpretation (no longer required)** (3 cr, Spring). The course provided practice in analysis and interpretation of existing datasets from clinical trials in a variety of diseases. Working with a faculty mentor and a statistician, students analyzed an existing dataset to answer a clinical question, and presented their findings in a noon seminar. The class was eliminated as a requirement because other courses (BMI 542 and 544) evolved to offer this content.
BMI 699 Multidisciplinary Patient–Oriented Research Seminar (1 credit, Fall). This course was developed for GPCI students and is required for MS students. Students evaluate the literature, and lead and present a medical or health topic, critically evaluating what is known and not known about the topic and providing strategies to improve knowledge. They were required to take the course for two semesters until 2013, when it became clear that one semester would suffice, given their daily work as health professionals critically appraising information, and their experience participating in journal clubs. The course meets by polling the professor and students for about half a semester’s worth of evening meetings. In 2013 and 2014, Dr. DeMets added an “elevator pitch” to the presentation requirement and added course content about participating in team science and current research on scientific communication.

Nursing 705 Seminar in Interdisciplinary Clinical Research Evidence (2 credits, Summer). Instructor, TA, Ebling librarian. Students consider the course invaluable for planning their eventual thesis defense. Students develop a clinical research question; search the literature using several databases and other sources across disciplines; manage sources of evidence with reference management software; critically review published clinical research; develop a search strategy for a meta-analysis; and present (verbally or by poster) their systematic work across the 8–week session. The librarian remains a resource throughout each student’s academic career.

The course was taught for several years by Karen Kehl, assistant professor in the School of Nursing. Dr. Kehl left UW in 2014 for a position at the National Institute for Nursing Research. Eneida Mendonça, associate professor of Biostatics and Medical Informatics has since been teaching it. Last summer’s TA was a GPCI MS graduate (Caroline Piskun) who is now pursuing a DVM. The Summer 2015 TA is GPCI PhD student Kimberly Shoenbill.

BMI 773 Introduction to Biomedical Informatics, formerly BMI 826 and 699 (3 credits, alternate Spring). The course is required for PhD students. MS students can take it as an elective to meet an “intermediate statistics” requirement. It introduces students to clinical bioinformatics and is the basis for further study in that area. The instructor is gradually moving much of the content of all her courses (across several programs) online, as appropriate.

Population Health Sciences 797 Introduction to Epidemiology (3 credits, Fall). The earliest graduates of the GPCI in the program (CIPP) that started in the Department of Biostatistics were the original Clinical Investigation students...
in this course. It remains required for GPCI MS and PhD students. The course meets requirements for students of several biomedical graduate programs and is popular among MPH students as well as Clinical Investigation students.

Accommodation in scheduling was provided by longtime instructor Halcyon Skinner for PharmD students, who have a course requirement whose time overlaps; they view some lectures online, with instructor approval. Dr. Skinner left for a job in industry after Fall 2013. With ICTR encouragement and resources, Ajay Sethi is moving PHS 797 to a time slot (4:00–5:15 PM) more convenient for our students. He also will teach the class in a blended format. Most lectures will be pre-recorded and available online. Almost all labs and the two exams will be completed in–person. Overall, the contact hours will be reduced by 50%; in–person meetings per semester will be reduced from 43 (51.25 contact hours) to 21 (25 contact hours). The change will be in effect for Fall 2015.

### Communication Science & Disorders 900 Research Career Development Seminar on Grant Writing

(3 credits, Spring). Required for a PhD in Clinical Investigation, the course is hosted in the College of Letters & Science. It provides exposure to and solutions for the issues involved in being a Principal Investigator, including attracting funding, hiring, supervising. It focuses on practical content for new investigators.

The course is delivered in a SMART classroom with a projection system connected to the internet. This technology allows students to review relevant NIH grant webpages and YouTube videos (e.g. demonstrating the grant review process). Lectures are delivered via PowerPoint. GPCI students take the class near the end of coursework. The addition of GPCI students enabled the instructor to use ICTR and Division of Continuing Studies funds to hire a Teaching Assistant and increase enrollment. The TA has been helpful in assisting the instructor’s home department students — for whom the course is required — who struggled with the grant writing assignments because their dissertation ideas were not yet formed. This dissatisfaction among CSD students is reflected in the 2009 course evaluations. The CSD Department has changed the requirement about when pre–doctoral students are allowed to take the course; that change coupled with the help of a TA has resulted in more positive evaluations.

### Evidence of Student Learning

#### Alumni Survey Results

Graduates feel “very competent” or “extremely competent” in the actions underlying the

---

**100% of graduates who responded to the question said they would recommend the Clinical Investigation program to other clinical research professionals.**
learning objectives, according to results of the 2014 survey of 5 PhD and 17 MS graduates. Twenty-one of 22 graduates responded for a response rate of 95%.

All 21 responders rated satisfaction on a 5 point Likert scale (1=very dissatisfied to 5=very satisfied), post–program, with the content and delivery of the required courses and the number of curricular opportunities (e.g. required courses, electives).

Seven people (one-third of responders) were “very satisfied” with the content of and eight were “very satisfied” with the delivery of the required courses (mean=4.29 for both questions). Thirteen were “satisfied” with the content, 11 with the delivery of the required courses. No one was more negative than “neutral” on the response scale, about any of the curriculum questions.

Many of the open–ended comments related to the curriculum were related to issues on which the program had already acted. For example, three comments suggested training in statistical software, and currently, a biostatistics professor is creating a new course. A respondent indicated difficulty with attending a required course mid–day. The instructor is moving to blended (online and in–person) course delivery, with fewer required
Graduates rated the program relatively high for imparting competence in various skills delineated in the learning goals specific to each degree (MS and PhD). Survey results are shown in the charts.

### E. CAREER OUTCOMES for GRADUATES

The career impact of earning the MS or PhD in Clinical Investigation was measured by a matrix of questions; however, current questions only scratch the surface of future effects, since the “oldest” graduate has held the MS for five years (former CIPP students Gleason and Hansen). Among our queries were whether graduates:

- Believe the GPCI degree has facilitated achieving “success in your field and having an impact in your field;”
- Work with a research team comprised of scientists from disciplines other than their own, and if yes, what disciplines;
- Have had an impact on their mentors’ research or other work.

Positive responses came from 17 among the 18 graduates who responded to the question “How has the program changed your professional output (e.g., publications, grants, mentees, etc.) since earning your degree?” The 18th noted “moderate change.” The entirety of the narrative response to this question is in Appendix, E1. Representative responses:

- “The program gave me the background needed to successfully publish papers, obtain grants and perform research. I doubt I would be where I am today without the degree.”
“Since my completion of my master’s degree, I have been able to increase my output in terms of publications and grants, which has exponentially increased my longevity in the field.”

“Papers have been published in higher impact journals, more opportunities to collaborate within and outside of UW campus.”

Representative Career Outcomes for MS Graduates, as Signified by Job Title

<table>
<thead>
<tr>
<th>Graduated</th>
<th>Name</th>
<th>Job Title at Graduation</th>
<th>Current Job Title and Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>2010</td>
<td>Dopp, John</td>
<td>Assistant Prof CHS, SOP</td>
<td>Associate Prof CHS, SOP</td>
</tr>
<tr>
<td>2013</td>
<td>Gallimore, Casey</td>
<td>Assistant Prof, CHS</td>
<td>Assoc Prof CHS, UW SOP</td>
</tr>
<tr>
<td>2009</td>
<td>Gleason, Carey</td>
<td>Scientist</td>
<td>Assistant Prof tenure track UW</td>
</tr>
<tr>
<td>2009</td>
<td>Hansen, Karen</td>
<td>Assistant Prof</td>
<td>Assoc Prof with tenure UW</td>
</tr>
<tr>
<td>2012</td>
<td>Jensen, Matthew</td>
<td>Trainee, ICTR</td>
<td>Assistant Prof CHS UW</td>
</tr>
<tr>
<td>2012</td>
<td>Kloepfer, Kirsten</td>
<td>Fellow</td>
<td>Assistant Prof, Indiana Univ</td>
</tr>
<tr>
<td>2011</td>
<td>Margolies, Amanda</td>
<td>Research Assistant</td>
<td>Lecturer, UW SOP</td>
</tr>
<tr>
<td>2013</td>
<td>McDowell, Kimberly</td>
<td>Assistant Scientist</td>
<td>Assistant Scientist UW</td>
</tr>
<tr>
<td>2013</td>
<td>Peissig, Peggy</td>
<td>Health Informatics Director, Security Health Plan</td>
<td>Director, Biomed’l Informatics Research Center, Marshfield Clinic Research Foundation</td>
</tr>
<tr>
<td>2012</td>
<td>Repplinger, Michael</td>
<td>Assistant Prof, non-tenure track</td>
<td>Asst Prof tenure track UW</td>
</tr>
<tr>
<td>2011</td>
<td>Rocque, Brandon</td>
<td>Resident UW</td>
<td>Assistant Prof Univ Alabama</td>
</tr>
<tr>
<td>2014</td>
<td>Schwantes, Elizabeth</td>
<td>Research Specialist</td>
<td>Senior Research Specialist</td>
</tr>
<tr>
<td>2010</td>
<td>Vardeny, Orly</td>
<td>Assistant Prof CHS, UW SOP</td>
<td>Assoc Prof CHS, UW SOP</td>
</tr>
</tbody>
</table>

Career Outcomes for PhD Graduates, as Signified by Job Title

<table>
<thead>
<tr>
<th>Graduated</th>
<th>Name</th>
<th>Job Title at Graduation</th>
<th>Current Job Title and Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>2012</td>
<td>Chang, Timothy</td>
<td>TL1 Trainee, Research Assistant</td>
<td>Neurology Resident, UCLA</td>
</tr>
<tr>
<td>2014</td>
<td>Magnan, Elizabeth</td>
<td>Family Medicine Fellow, Research Assistant</td>
<td>Assistant Prof tenure track UC-Davis</td>
</tr>
<tr>
<td>2012</td>
<td>Obasi, Chidi</td>
<td>Clinical Research Fellow</td>
<td>Assoc Research Specialist</td>
</tr>
<tr>
<td>2013</td>
<td>Peissig, Peggy De Long</td>
<td>Health Informatics Director, Security Health Plan, Marshfield</td>
<td>Additional Title: Associate Research Specialist, Marshfield Clinic Research Foundation</td>
</tr>
<tr>
<td>2012</td>
<td>Yang, Richard</td>
<td>TL1 Trainee, Research Assistant</td>
<td>Pathology Resident, UW-Madison</td>
</tr>
</tbody>
</table>
Whether graduates have had an impact on mentors’ research or other work had a response from 9 graduates, 7 of whom said yes, in publishing, grant writing, discussion of graduate and mentor’s research design and disease impact, and acting as co-investigator on funded R01s.

Ten graduates responded to whether the program facilitated achieving success or having an impact in their fields. Nine said yes, and 1 “possibly.” A typical comment: “Yes, I’ve been able to conduct research in a methodologically sound manner and am in the process of publishing multiple articles.”

Graduates offered comments that employers believed that the graduate was well–trained because of the Clinical Investigation degree and that this helped in hiring and promotions.

A telling measure of how graduates function as clinical and translational researchers is whether they work in a multidisciplinary team that might include, for example, a biostatistician, research manager, oncologist, medical resident, and more. One hundred percent of PhD graduates and 69% of MS graduates indicate that they work in a cross–disciplinary research team.

F. FUNDING PATTERNS for STUDENTS

Student Funding Sources in Order

<table>
<thead>
<tr>
<th>Source</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Departmental traineeships</td>
<td>13</td>
</tr>
<tr>
<td>- 6 ICTR KL2 postdoctoral traineeships</td>
<td></td>
</tr>
<tr>
<td>- 7 other</td>
<td></td>
</tr>
<tr>
<td>Self-funded or partially self-funded</td>
<td>13</td>
</tr>
<tr>
<td>- 8 non-faculty employment</td>
<td></td>
</tr>
<tr>
<td>- 5 NIH awardees: R01, R21, F30, and two K23</td>
<td></td>
</tr>
<tr>
<td>Research assistantships</td>
<td>11</td>
</tr>
<tr>
<td>Departmental faculty employment</td>
<td>7</td>
</tr>
<tr>
<td>Departmental fellowships</td>
<td>4</td>
</tr>
<tr>
<td>Departmental teaching assistantships or positions</td>
<td>4</td>
</tr>
<tr>
<td>Departmental residency</td>
<td>2</td>
</tr>
<tr>
<td>Foreign government scholarship</td>
<td>1</td>
</tr>
</tbody>
</table>

The ICTR’s pre–doctoral training grant is not a major mechanism for GPCI student funding because it is restricted to full time students earning the Clinical Investigation PhD and PhD Minor. Most of our students study part time.
Twelve out of 38 students’ funding is a combination of these mechanisms. Therefore, the total in the chart exceeds the number of students. F1 in the Appendix contains the full list of students and funding sources.

G. ADMISSIONS, DEGREE COMPLETION PATTERNS, and RECRUITING

Admissions

GPCI applicants submit the Graduate School online application. As a supplemental application, they submit an NIH biosketch, resume, or curriculum vita to the program. A multi-school/Marshfield faculty committee, the Admissions and Recruiting Subcommittee (of the program Executive Committee) reviews and discusses applications in person annually. The committee votes by e-mail about transfers from other graduate programs or off-cycle admissions, though this is rare. Applicant interviews are scheduled as appropriate. We state our admissions criteria on our website. The procedure for admissions is in Appendix G1. The membership of the subcommittee is listed in D1.

Two major admissions requirements set the GPCI apart from most biomedical graduate programs on campus:

1. A background including at least a health professional degree: MD, DO, DDS, PharmD, DVM, PhD, BSN, BS in an Engineering field or other post-baccalaureate degree in a clinical or biomedical field. This can be discussed case by case; rarely, applicants with a BS were recommended for admission who were not simultaneously completing the MD.

2. Identification of a faculty advisor and research program that aligns with the student’s patient-oriented research interests and career goals.

These requirements exist to identify applicants most likely to succeed in the program. It is important upon entry that GPCI students have at least a basic understanding of how clinical and translational research fits with their career goals. The more detailed a Personal Statement that an applicant can write, the more the admissions committee is comfortable with whether the applicant is a good fit with the GPCI. Requiring a faculty mentor and research project description unfortunately eliminates international students who are not already on campus.

As compared with pre-program estimates, actual enrollment in the MS degree is higher than expected and is on target for the PhD degree. Students have graduated earlier than we anticipated (See H. Degree Completion Patterns). We expected five people per year to enter the MS program, for a total of 25 in the first five years. The actual total: 29. We estimated that the PhD program would ramp up slowly, with two people entering in each of the first two years. That is exactly what happened. We expected four people in each of the next two years; actual enrollees were three students and four students. In the fifth year, we estimated that six people would enter, but three did. We have a PhD retention rate of 85.7% in the reporting period, and expect to attract and retain more PhDs now that 10 fewer credits are required to earn the degree. We expected no PhD graduations until two in the fifth year, but five have graduated already.
Some 35 people have enrolled in the MS program, and 17 in the PhD program. The largest class to matriculate was in 2009, with 13 MS and 2 PhD entries; the smallest in 2010, with 3 MS and 2 PhD students enrolling. We are pleased with the MS program’s success, particularly the MS enrollment and productivity of MS and PhD students. The chart below shows students admitted by year and program, as well as graduates, withdrawals, total number continuing, and the status of each GPCI enrollee by year.

<table>
<thead>
<tr>
<th>Clinical Investigation MS Student History</th>
<th>2008</th>
<th>2009</th>
<th>2010</th>
<th>2011</th>
<th>2012</th>
<th>2013</th>
<th>2014</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enrolled</td>
<td>2</td>
<td>13</td>
<td>3</td>
<td>9</td>
<td>2</td>
<td>4</td>
<td>2</td>
<td>35</td>
</tr>
<tr>
<td>Graduated</td>
<td>2</td>
<td>9</td>
<td>2</td>
<td>3</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>17</td>
</tr>
<tr>
<td>Active</td>
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<td>0</td>
<td>0</td>
<td>2</td>
<td>1</td>
<td>4</td>
<td>1</td>
<td>7</td>
</tr>
<tr>
<td>Withdrew</td>
<td>0</td>
<td>4</td>
<td>0</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>6</td>
</tr>
<tr>
<td>Transferred (PhD)</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Transferred (Certif)</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Clinical Investigation PhD Student History</th>
<th>2009</th>
<th>2010</th>
<th>2011</th>
<th>2012</th>
<th>2013</th>
<th>2014</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enrolled</td>
<td>2</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>3</td>
<td>4</td>
<td>17</td>
</tr>
<tr>
<td>Graduated</td>
<td>2</td>
<td>0</td>
<td>3</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>5</td>
</tr>
<tr>
<td>Active</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>4</td>
<td>2</td>
<td>4</td>
<td>10</td>
</tr>
<tr>
<td>Withdrawed</td>
<td>0</td>
<td>2</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>3</td>
</tr>
</tbody>
</table>

Although we technically cannot count them, two UW–Madison medical students earned dual degrees — Doctor of Medicine and PhD in clinical investigation — by a special graduate committee in 2006, before the PhD program in Clinical Investigation existed. That story is on page 5).

The following table shows the productivity, as measured by publications and grants, of 14 students who entered the MS program in three of the early years of the program. Pre–MS, two of them received five grant awards (four extramural and one intramural). During and post–MS, eight of the 14 scholars received 17 grant awards (three extramural and four intramural).

<table>
<thead>
<tr>
<th>Productivity of 14 MS Students 2010-2012</th>
<th>Pre-MS</th>
<th>During MS</th>
<th>Post-MS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Publications (#/Scholar/2y)</td>
<td>1.7±0.3 (8/14)</td>
<td>3.3±0.8 (12/14)</td>
<td>4.0±0.7 (11/14)</td>
</tr>
<tr>
<td>Grants (Award $)</td>
<td>$187,126 (2/14)</td>
<td>$8,225,376 (5/14)</td>
<td>$3,378,986 (5/14)</td>
</tr>
</tbody>
</table>

Key measures of GPCI success are whether graduates are working in multidisciplinary research teams and how they are having an effect on their faculty mentor’s research, as well as student and alumni success in publishing and attracting funding. We have highlighted three of these measures in this report because GRE scores and GPAs are not comparable measures for the GPCI and other UW–Madison graduate programs. The GPCI admissions committee does look at GRE scores and GPAs; however, applicants are viewed not only holistically, but with a focus on GPCI program fit. The GPCI does not require GREs if the applicant has a graduate or medical professional degree from a U.S. institution. GPAs are consistently high because most applicants have already earned a terminal degree.
Degree Completion Patterns

The average Time to Degree for the GPCI MS is 2.35 years. The average for the GPCI PhD is 2.80 years. These are spectacular results, and reflect an uncommonly motivated student population. They are phenomenal when one considers that most GPCI students study part time. There are, however, caveats:

1. The averages reflect actual enrolled semesters in the GPCI program. Evaluating efficiency toward graduation by the number of semesters in which a student’s plan was the GPCI (204M) ignores that many of the GPCI students completed requirements as Special Students prior to admittance to the program.

2. The details of what actually happened for the graduates each year are important. For example, because of other life demands in this age group (such as having children), three of the MS graduates earned the degrees despite taking a semester off.

The details for the five PhD graduates look like this:

- Tim Chang, 3.0 years. As an MSTP student, Tim had four years for the graduate degree but did not need all of it.
- Beth Magnan, 3.0 years. Beth earned her MD here in 2003 and returned for the PhD in Clinical Investigation in Summer 2007. She worked as a clinical fellow in Family Medicine as well.
- Chidi Obasi, 1.5 years. Chidi entered with an MS in Population Health Sciences, where he took required courses shared with Clinical Investigation.
- Peggy Peissig, 2.5 years. Peggy transferred to Clinical Investigation from the PhD program in Industrial Engineering in 1999. She studied with Prof. David Page advising, while commuting from Marshfield.
- Richard Yang, 4.0 years. Richard was an MSTP student. It is exceptional to complete any reputable PhD program in the country in 4 years; 4 years is the time it took the GPCI’s slowest PhD graduate. Richard continues working in the lab of his graduate primary adviser, Paul Sondel.

The background for the MS years to completion average, by year of student entry:

- 2008, 1.0 year (2 students, both of whom completed coursework in the CIPP program prior to GPCI approval)
- 2009, 2.38 years (9 students)
- 2010, 2.25 years (2 students)
- 2011, 2.75 years (4 students)
- 2012 and 2013, Not Applicable (students still active)
- 2014, 0.5 years (1 student, who completed half the requirements as a Special Student and the other half in the last Summer and Fall, including the thesis defense, due to visa issues)

Reasons for Withdrawing. Because the students are health professionals, work conflicts are the most common reason for withdrawing. Additional reasons have been taking a job outside Wisconsin (MS student), and potential deleterious effects on obtaining tenure. In contrast, some of our graduates have commented that earning the degree has been beneficial to earning tenure.
Six people have withdrawn from the MS program (later than the first semester). For two of them, only a small amount of coursework and a thesis remained, but they said their schedule did not allow degree completion. An additional student exited for lack of time but earned our Certificate.

Another switched from the MS program to pursue a PhD, but decided in the first PhD semester to stop. He joined 2 other PhD withdrawals. One of these, a research manager at Children’s Hospital of Wisconsin, Milwaukee, left the PhD program after a year, citing funding reasons, and enrolled in a UW–Milwaukee PhD program. She said she had intended to pay tuition through a research or graduate assistantship at UW–Madison, but neither materialized. The third student left the PhD program in the first semester for a medical reason.

**Recruiting**

The GPCI recruits from among health professionals from the ICTR partners: College of Engineering, Schools of Medicine and Public Health, Nursing, Pharmacy, and Veterinary Medicine, and Marshfield Clinic. Ten PhD and seven MS students are currently enrolled. For Fall 2015, five students (four PhD, one MS) have accepted admissions offers. These are solid, if not soaring, numbers for a five/six–year old applied research degree program that recruits primarily from this campus.

The number of domestic (non–international) non–targeted enrollees has steadily decreased from 94% in the academic year starting Fall 2009 to 61% in Fall 2014. The number of domestic targeted minority enrollees has increased from 9% in 2011 to 17% in Fall 2014. These two measures are “trending” in the right direction; however, we aim to increase diversity and remain active in encouraging underrepresented student applications.

As the visibility and value of our graduate program grows, new faculty are now negotiating for funding to earn the degree, during the hiring process and some full time professional degree (PharmD) students are interested in pursuing the program as a dual degree, informally. This is key to providing NIH funding, as these are full time pre–doctoral students.

Dual degrees combining professional doctoral programs and the Clinical Investigation program are in various stages of discussion.

Dual degree options and programs that include the GPCI increase career options for DVM, PharmD, Nursing, and Engineering students and further build the pool of full time GPCI PhD students for potential NIH funding. The Veterinary Medicine website publicizes the possibility of earning dual degrees with GPCI (without a formal program) at [http://www.vetmed.wisc.edu/dvm-students/current-students/dual-degrees](http://www.vetmed.wisc.edu/dvm-students/current-students/dual-degrees). A PharmD/Clinical Investigation MS or PhD program has been discussed between the two programs regularly, and progress has been made. A PharmD student has been admitted to the GPCI MS program for Fall 2015, having finished our professional certificate. Two more PharmD students are likely to follow the same informal path to dual degrees; they are new students in our professional certificate program. The PharmD students are seeking increased research training. The dual degree will expand their career options beyond what might be open to them if they earn only a Minor or Certificate in Clinical Investigation. The Executive Committee discussed how the GPCI could
better serve nursing students at the December 2014 meeting. At least 16 students have earned and 13 are earning a Minor in Clinical Investigation while earning a PhD in other UW–Madison graduate programs. We expect that our new, lower number of credits will attract more students to pursue the PhD Major.

Challenges in recruiting include (1) NIH TL1 funding would include more full time PhD students if we could find them (thus the professional dual degree recruiting efforts); (2) that diversity in the recruiting pool is tied to success in recruiting diverse faculty to UW–Madison (an institutional challenge); and that as a marketing tool, the graduate program website is not visible enough, as currently embedded in ICTR’s website.

The Executive Committee and Admissions and Recruiting Subcommittee continue to examine ways to improve recruitment. Our current primary recruiting activities include: Talking in person and by direct e-mails with advisers of potential students, fellowship and traineeship directors, and department chairs; and word of mouth by current students and alumni, many of whom remain on campus; improving marketing materials (publicity examples are on the GPCI website and in G2); and reviewing course rosters and contacting students who seem to be interested in the field.

We have identified our target population, but we have little systemic research so far on what recruitment strategies have been successful. Our prospective students work in clinics with patients (human or animal) full time, hold a terminal degree in engineering, medicine, nursing, pharmacy, veterinary medicine, and want formal training in how to be a clinical investigator to improve their careers. We are recruiting a “tribe” or culture, as well as an individual student. We need to know what message (or lack of) the tribe has already heard; for example, do surgery residents know that they could earn an MS in Clinical Investigation in two years part time? We believe that all partner schools/college have had a culture change to include awareness of the ICTR graduate programs and other educational opportunities.

H. SELF-REVIEW RECOMMENDATIONS

Immediate. Look closely at the PhD and MS Learning Goals (planned for May 2015 meeting of the Executive Committee).

Future. Discussions are pending by program leaders, administrators, Executive Committee and TL1 Advisory Committee members about three factors to address regarding the program's future. Phrased as a question: Is it appropriate to continue to recruit students who work full time and therefore study part time, given that the program offers no funding and lacks full time PhD students for the NIH funding available? If the answer is yes, these recommendations follow:

- Look closely at the alumni survey results (tentatively planned for Summer and Fall 2015 meetings of the Executive Committee).
- Discuss a draft recruiting plan (tentatively planned for Summer and Fall 2015 meetings of the Executive Committee).
  - Identify barriers to successful recruiting and address each one. Determine what each recruiting pool (tribe) has received about the program to determine the reality of the recruiting needs.
Determine whether visa issues make GPCI study unattractive to clinical and translational researchers who are here on temporary work visas, and whether campus can do anything about it.

- Gather information and brainstorm with campus, partner schools, and CTSA colleagues about recruiting underrepresented health professionals to training in the field of Clinical Investigation. We are not content with simply stating that paltry minority recruiting of clinician and translational scientists is a national problem.
- Possibly convene a CTSA consortium discussion platform for addressing recruitment of clinicians and other health professionals to biomedical research training.
- Identify additional sustainable innovative educational activities that will benefit our students most (discussions with instructors, campus leaders, and CTSA education practitioners).
Date: June 16, 2015

To: Seth Blair, Professor of Zoology (UAPC Member, Committee Chair)
    Lisa Forrest, Professor of Veterinary Medicine (Provost Appointee)
    Caroline Alexander, Professor of Oncology (Graduate Faculty Executive Committee appointee)
    Lauren Trepanier, Professor of Veterinary Medicine (Consultant - Program Representative)

From: Sarah C. Mangelsdorf, Provost and Vice Chancellor for Academic Affairs

RE: Five-Year Review – MS/PhD Clinical Investigation

Thank you for agreeing to serve on the five-year review committee for the MS/PhD in Clinical Investigation.

Professor Seth Blair, a member of the University Academic Planning Council, has agreed to chair the committee. He will contact all of the committee members to arrange the proceedings of the review. Professor Lisa Forrest, who chaired the committee that reviewed the original proposal for this program, will serve as the provost’s appointee. Professor Caroline Alexander will serve as the representative of the Graduate Faculty Executive Committee. Professor Lauren Trepanier will serve in a consulting role as a representative of the program.

Jocelyn Milner, director of Academic Planning and Institutional Research, will also participate as a consultant. Her experience with these reviews and the original program planning helps set a foundation for consistency in how the reviews are handled.

I ask that you conduct the review and send your report to me by November 1, 2015. I know that this charge is coming to you in the middle of the Summer and that you have many other commitments which may impact the timeline. Please check with Jocelyn if you need more time.

The overall purpose of the review is to confirm that the program is on track, serving students well, and should be continued. The review committee is also invited to provide the program with advice for improvement.

More specifically, the purpose of the five-year review is to:

a. Determine whether the goals and objectives as stated in the original program proposal were met and evaluate if the program is meeting standards of quality that are expected based on the original proposal.
b. Confirm that the program is important to be delivered at UW-Madison and understand the program’s relationship to other programs at UW-Madison. Are other programs positively or negatively impacted? Are connections with other programs as planned in the original proposal developing as envisioned?

c. Determine if the resource implications of continuing the program are appropriate.

d. Offer the program faculty and/or the dean(s) any advice for program improvement and summarize any actions for follow-up or attention.

e. Provide an explicit recommendation as to whether the program should be continued.

Documents that serve as the basis for the review are attached:

- The self-study, which was prepared by the program faculty and staff.
- The dean’s cover memo and summary of key issues.
- The executive summary of the original proposal that was considered by the Board of Regents when the program was approved and the full authorization to implement proposal.
- UW-Madison five-year review guidelines, which includes some guidance for the committee on conducting the review.

Typically, review committees meet once or twice to review the documents; the review may also include additional meetings with faculty or students as you deem appropriate.

After you complete your review, please prepare a short report (2-4 pages) and send it to me (provost@provost.wisc.edu). Jocelyn Milner will arrange for the next steps, which include a presentation of the review to the GFEC and to the UAPC.

Please keep Jocelyn informed about the progress of your review and include her when you schedule the review committee meeting. As noted above, contact her if you wish to discuss the time line for the review or need help with procedural questions, examples of previous review reports, additional quantitative data, other information, or any other assistance completing this review. She can also arrange for you to receive a set of paper materials if that is what you prefer.

Again, I very much appreciate your willingness to accept this assignment.

Attachments

Copy: Jocelyn Milner, Director of Academic Planning and Institutional Research
Sarah Kuba, Academic Planner, APIR
Marc Drezner, ICTR
Sally Wedde, Clinical Investigation Program
Daniel Kleinman, Graduate School
Marty Gustafson, Graduate School