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Clinical Pharmacology Registrar Training Program

Welcome to the Division of Clinical Pharmacology. We hope that you will find your 4 years of training rewarding. This summary will orientate you as to what is expected from you during the next 4 years.

In order to become a registered Clinical Pharmacologist, you have to be accepted as a Fellow of the College of Clinical Pharmacologists of South Africa by the College of Medicine of South Africa [FCCP(SA)] and obtain your Master of Medicine in Clinical Pharmacology (MMed) from the University of Stellenbosch.

During the next 4 years we will provide you with a fully accredited training programme to become a Clinical Pharmacologist. To successfully complete this programme, you should meet the following requirements at the end of each year:

Activity	Year 1				Year 2				Year 3				Year 4			
	3	6	9	12	3	6	9	12	3	6	9	12	3	6	9	12
Module I: Principles of Clinical Pharmacology																
FCCP Part 1 exam																
Module II: Applied Clinical Pharmacology																
FCCP Part 2 exam																
Module III: Research Assignment																
Module IV: Research methodology																
3-monthly portfolio review																

FCCP (SA)
To obtain the FCCP (SA) you have to pass two exams: the Part I focuses on the basic science of clinical pharmacology and the Part II on the clinical aspects of clinical pharmacology and therapeutics. You are eligible to write the Part I exam after you have completed 15 months of your registrar time; and Part II after you have completed 3 years of your registrar time. Please visit the College of Medicine of South Africa (CMSA) website (www.collegemedsa.ac.za) for more details on the requirements as well as the curriculum. You have to complete a portfolio that is downloadable from the website. The portfolio will be reviewed by the College to determine your eligibility to participate in the

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Part II exam. The completion of your portfolio is a continuous process until you have successfully passed the Part II exam. The portfolio will be reviewed every 3 months by your mentor in the Division of Pharmacology to determine your progress. This may include an evaluation (written or oral) at the end of every 3 month rotation.

Basic course work modules
The Division of Pharmacology offers 4 short courses in the field of Pharmaceutical Medicine and a BScHons Pharmacology course. The Faculty of Health Sciences offers courses on research methodology, GCP, ethics and epidemiology/statistics. We suggest that you participate in these programmes to assist you with the preparation for the Part I and Part II exams. The research methodology and GCP courses are compulsory parts of your module IV.

Research assignment
You have to submit a research assignment relevant to the field of Clinical Pharmacology as part of the requirements to be awarded the MMed in Clinical Pharmacology.

The process

- You will find the relevant requirements for the MMed dissertation in the most recent Faculty Yearbook. Please familiarise yourself with the document *Stellenbosch University, Faculty of Health Sciences, Provisions for Research Assignments of Structured Master's Program*.
- Identify a project and study leader and sign a contract with your study supervisor, clearly setting out time lines and responsibilities. Start early and stick to deadlines. A completed project is a prerequisite (Stellenbosch University candidates) for registration for the FCCP part 2 exam. The Head of the Department of Medicine is required to verify that you have completed your research project.
- Do a preliminary literature search and discuss the feasibility of your proposed project with your study leader and various experienced researchers.
- Prepare a protocol and apply for ethics approval from the HREC. For more information visit the following webpage: http://sun025.sun.ac.za/portal/page/portal/Health_Sciences/English/Centres%20and%20Institutions/Research_Development_Support/Ethics.
- Finish data collection timeously.
- Prepare a dissertation (approx. 80 pages). Several revisions are often required. The dissertation should be handed in by your supervisor to the chairman of the postgraduate committee (with an accompanying cover letter).
- The postgraduate committee will appoint one internal and one external examiner. The dissertations (first draft handed in to the postgraduate committee) will be graded, and changes may be suggested. These changes should be addressed in the final (second) version – only then will the marks be captured (i.e. the research component is only considered complete when the second (or more) version is found to be acceptable by the postgraduate committee).
- You will give an oral presentation on completion of the research assignment, and you are expected to publish the research project in an accredited peer-reviewed journal.

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Time frame

- We suggest that you discuss and plan your project with your supervisor in your first year of training and perform the study and write-up your findings in your 3rd year. The dissertation (as stated above) has to be handed in prior to registration for the final exam.

Assistance from the Department/Faculty

- In an attempt to assist registrars, all students will be expected to complete the *Short course on Research Methodology* which is a 12 weeks (once a week) course provided by Faculty every year.
- Visit the University Stellenbosch website at www.sun.ac.za/international/pgskills for various courses which may help you with specific areas of your research.
- The online *on.track planner tool* has been developed as an interactive resource to guide postgraduate students through the research process. It is available at: www0.sun.ac.za/ontrack (yes, with the 0 after the www)
- Presentation at a Thursday Departmental Academic meeting gives the registrar an opportunity to get input from the other members of the department about study design, potential pitfalls etc which may save the registrar many hours of frustration. The Head of Department will only sign the HREC application form once the study has been discussed at the Academic Meeting. The research protocol must be presented to and approved by the relevant Faculty Committee and by the Health Research Ethics Committee before commencement.

Overtime

You will be expected to participate in the on-call roster for the Poison Information Centre (PIC) as well as the Clinical Pharmacology service of the hospital, which will include weekend duties. You will also need to set aside time at weekends for self directed learning and development of training material, as well as for reading journals.

PIC on-call responsibilities:

This will consist of 3 weekdays after hour calls (16h30 through 08h30) and 1 weekend day (08h30 through 08h30) a month to advice on toxicology related queries. You will be provided with electronic references and the information databases to manage the calls. You will be on call with a consultant who will be available to assist you with complicated cases.

Clinical Pharmacologist on-call responsibilities:

- To act as the clinical consultant for the PIC as needed. PIC will take the calls first and refer when a clinical opinion is required.
- To assist the Clinical Pharmacology laboratory (see TDM interpretation)
- To respond to medicine related queries from hospital colleagues including:
    - advice on rational selection of medicine
    - dosing in special populations (obesity, renal impairment, liver impairment, pregnancy, lactation, paediatrics, giving drugs via NGT etc)
    - adverse drug reaction assessment

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  - polypharmacy with potentially multiple drug-drug interactions
  - assist to fast-track urgent Pharmacy & Therapeutic Committee requests
- Therapeutic drug monitoring (TDM) interpretation

This will entail you visiting the TDM laboratory at least twice a day in the morning and again at around 15h00. You will be assisted by the Clinical Pharmacologists when on call. Your duties will be to review abnormal laboratory results and contact clinicians as required. Please make sure that you are familiar with the various aspects of TDM and how it impacts on the work of a Clinical Pharmacologist. You will be expected to understand the aspects of a good laboratory practice relevant to the TDM laboratory and its day to day functions.

Ward consultations
On a Monday during the 08:30 registrar meeting arrangements will be made to allocate a registrar to review the Clinical Pharmacology consultations in the hospital which may include:

- polypharmacy with potentially multiple drug-drug interactions
  - advice on rational selection of medicine in this context
- dosing in special populations (obesity, renal impairment, liver impairment, pregnancy, lactation, paediatrics, giving drugs via NGT etc)
- adverse drug reaction (ADR) assessment
- toxicology consultations
  - advice on management of toxic ingestions of medicines

Medical student teaching and training
You will be expected to assist with the teaching of medical students. The teaching will consist of didactic lectures and student orientated ward rounds. As far as possible, we will allocate lectures that align with your stage of training. Every year you will be allocated new teaching topics to allow you to cover a broad range of topics. You are expected to attend the lectures of the senior pharmacology staff when you start your time in Clinical Pharmacology and before you take over a lecture from a colleague. Before you teach a topic for the first time, a senior lecturer must review the prepared contents.

The ward rounds will stimulate the teaching of Clinical Pharmacology around the bedside. Registrars and/or pharmacology lecturers will facilitate the student ward rounds on Tuesday and Thursday afternoons. You will be expected to participate in at least 1 of these ward rounds weekly. The selected ward round case will be focused to consolidate student knowledge and understanding.

Registrar teaching
Interactive discussions will take place between you and the academic staff of the Division on a regular basis during journal clubs and patient case discussions. Furthermore, you will be expected to participate in the joint University of Cape Town and Stellenbosch University registrar teaching programme on Monday afternoons.

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Clinical work
Assistance with clinical work will form 25% of your training period. During the first year of your rotation, you will spend dedicated time attached to a medical firm with 3 monthly rotations. During years 2 and 3 you will rotate through one of the following outpatient clinics once a week every 3 months: endocrine, renal, cardiology, dermatology, neuropsychiatry, infectious diseases (Dr Taljaard firm), paediatrics, oncology-haematology. During year 4 you can choose rotations of your choice. These clinical commitments will be arranged with the Department of Medicine and other clinical Departments as appropriate.

Journal club
You are expected to present a journal article on a regular basis at the Journal Club of the pharmacology postgraduate students. Pre-part I registrars are expected to present articles from focused clinical pharmacology journals such as *The British Journal of Clinical Pharmacology* and *Clinical Pharmacology and Therapeutics.* Pre-part II registrars will focus more on general medicine journals such as *The Lancet* and *The New England Journal of Medicine.*

Pharmaceutical and Therapeutic Committee (PTC)
Part of your training will be to participate in the Tygerberg Hospital PTC meetings. Your role at the PTC will initially be as observer, but after 3 months, you will be required to assist with the assessment of motivations for formulary inclusion as feasible.

Clinical trials
As part of your training you will actively participate in clinical trials performed by the Tiervlei Trial Centre (TTC) located at Karl Bremer Hospital under supervision by one of the investigators. The trials may run after hours.

Ethical review of clinical trials
You will once a month review the ethics submission for a clinical trial on behalf of the Health Research Ethics Committee (HREC), assessing both the scientific merits of the study and ethical aspects. You will review the clinical drug trial submissions with the support of a Clinical Pharmacologist. This will allow you to develop an appreciation for the ethical conduct of clinical trials as well as insights into Good Clinical Practice (GCP).

Department of Medicine activities
The Division of Pharmacology forms part of the Department of Medicine. You are expected to attend the Monday morning Department Meeting, the Thursday afternoon Academic Meeting and the Grand Ward Round on a Friday afternoon. You will be expected to present cases from time to time on a rotational basis at the Academic Meeting.

The basic lay out of your work week will be as follows:

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	Monday	Tuesday	Wednesday	Thursday	Friday
08:00	Dpt of Medicine business meeting				
08:30	Registrar meeting				
09:00	TPIC – review of toxicology cases	Clin Pharm journal club (all)			
10:00					
11:00					
12:00			Div of Clin Pharm meeting		
13:00	Joint UCT & SU registrar teaching	Undergraduate Clin Pharm bedside ward rounds		Undergraduate Clin Pharm bedside ward rounds	Clin Pharm journal club (registrars)
14:00					**14:15** Grand ward round (A5W)
15:00					
15:30				Dpt of Medicine Academic Meeting	
17:00					

Text books and prescribed reading
The reading of journal articles forms a critical basis for life-long learning and evidenced based decision making. It is essential that journal reading becomes part of your professional life. Registrars are advised to study the following text books and leading medical/clinical pharmacology journals:

Text books (latest editions):

- Katzung, BG. Basic & Clinical Pharmacology. Lange
- Goodman and Gilman's. The Pharmacological Basis of Therapeutics. McGraw Hill
- Walley T et al. Pharmacoeconomics. Churchill Livingstone
- Strom BL. Pharmacoepidemiology. John Wiley
- South African Medicines Formulary (SAMF).
- Straus S et al. Evidence-Based Medicine: How to Practice and Teach EBM. Churchill Livingstone
- JP Griffin, J O'Grady, Textbook of Pharmaceutical Medicine. Blackwell
- B Spilker, Guide to Drug Development: A Comprehensive Review and Assessment. Lippincott Williams Wilkins

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Reviews and seminal articles in leading medical and pharmacology journals, such as:

- New England Journal of Medicine
- Lancet
- Pharmacological Reviews
- Clinical Pharmacology & Therapeutics
- Annual Review of Pharmacology & Toxicology
- Drug Safety
- Annals of Pharmacotherapy

Homepages of FDA, EMA, ICH (http://www.fda.gov/; http://www.ema.europa.eu/ema; http://www.ich.org/)

We wish you lots of success with your training. We will support you wherever we can, but ultimately you are responsible for your learning. The registrar programme is coordinated by Prof Bernd Rosenkranz and any problems or queries should first be directed to him.

With best wishes for a successful and pleasant time in the Division of Pharmacology.
Tygerberg, 27 January 2014.

Prof Bernd Rosenkranz & Dr Eric Decloedt

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Overview of Stellenbosch University Clinical Pharmacology registrar training		
Activity rational	**Activity**	**Implementation**
Regulation 1.3.1 CMSA: FCCP *Advise on drug policy*	• PTC & PPTC involvement • Workshops dedicated to drug policy	• **TBH PTC observer** *Involvement after 6 months of starting the program* *Formal invitation required from TBH CEO* • **PPTC observer** *Involvement depends on progress.* *Formal invitation required from PPTC chair* • **Workshops dedicated to drug policy** *When opportunity arises, depends of progress*
Regulation 1.3.2 CMSA: FCCP *Advise on the management of patients*	• Clinical pharmacologist on call for TBH • Ward consults as required • TDM interpretation & feedback to TBH • PIC involvement • Clinic rotation • Clinical Pharmacology teaching	• **TBH on call rooster** *Implementation Feb 2014. 7 day cycles per on call person* • **Ward consults** *Implementation March 2014* • **TDM interpretation & feedback to TBH** *Implementation Feb 2014* • **PIC involvement** *On call for PIC end of Jan 2014. (Number of calls to be determined)* *Backup for PIC Feb 2014* • **Clinic rotation** *25% of time (1 clinic per week)* *Y1: General medicine firm attachments – Dr Manie firm & Dr Schrueder firms (3 monthly rotations). General paediatrics firm attachment (3 month rotation).* *Y2 & Y3: Select a 3 monthly rotation from the following: endocrine, renal, cardio, derm, neuropsych, ID (Dr Taljaard firm), paeds, oncology- haematology* *Y4: Clinics of choice* • **Clinical Pharmacology teaching** *Weekly joint academic meeting with UCT: registrars to review relevant Clinical Pharmacology topics* *Psychopharmacology ward rounds ?SU & UCT collaboration Weekly presentation of up to date literature at div of Clin Pharm journal club* *Selected non-degree modules: statistics, pharmacoeconomics, pharmacoepidemiology, critical appraisal etc (to be defined early next year after finalising teaching program with UCT)*

Regulation 1.3.3 CMSA: FCCP *Acquire new medicines information and critically evaluate its quality and utility*	• EBM • PTC	• **EBM** *Joint teaching with UCT* *MIC rotation: early 2014* *Selected teaching as part of the pharmaceutical medicine course Center for Evidence Based Health Care* • **PTC** *As above*
Regulation 1.3.4 CMSA: FCCP *Function as an effective team member in the broad context of health care*	• Ward consults • PTC • Clinic rotation etc	As above
Regulation 1.3.5 CMSA: FCCP *Play an active role in training other health care workers*	• Undergraduate teaching • Medicine academic meetings • CME • CID academic meetings	• **Undergraduate teaching** *Undergraduate teaching ward rounds: Feb 2014* *Undergraduate lectures: involvement in second half of 2014* • **Medicine academic meetings** *Participation from Feb 2014* • **CME** *Participation as needed* • **CID** *Participation in the infectious diseases academic meetings*
Regulation 1.3.6 CMSA: FCCP *Engage in research*	• HREC review • Own research • Tiervlei rotation • SU Research Training seminar • GCP	• **HREC review** *Involvement from Y2* • **Own research** *As required by HPCSA, suggested involvement from Y2* • **Tiervlei rotation** *Rotation at a phase I research unit* • **SU Research Training seminars** *Attend as scheduled by the Faculty* • **GCP introductory course** *Depends on involvement*