

1. **NAME**
FAMILY CENTRE for RESEARCH with UBUNTU (FAM-CRU) /
FAMILIE SENTRUM vir NAVORSING met UBUNTU (FAM-KNU)

2. **STATUS**

The unit began as the Children's Infectious Diseases Clinical Research Unit (KID-CRU) in January 2002 and officially opened in September 2003 as a clinical trial unit. It was established through external funding as a result of four simultaneously successful funding applications between 2000 and 2002, which provided the initial essential infrastructure and personnel. The original focus was on HIV and tuberculosis co-infection in children and their mothers. Over time, the scope has broadened to include other infectious diseases. To accommodate the inclusion of adults in January 2013 through a successful application to the National Institute of Allergy and Infectious Disease (NIAID), KID-CRU's name changed to FAM-CRU.

CURRENT SITES:

- a. FAM-CRU's main center is situated in Ward J8, immediately adjacent to the Family Clinic for HIV (H8) in Tygerberg Academic Hospital.
- b. Michael Mapongwana – modular clinic (from 2007)
- c. Kraaifontein Community Health Center -modular clinic (from 2014)
- d. Worcester Provincial Hospital – modular clinic (from Nov 2017)

3. **AFFILIATION TO STELLENBOSCH UNIVERSITY**

FAM-CRU, a type 1 unit, is situated within the Department of Paediatrics and Child Health (OU code 1803) within the Faculty of Medicine and Health Sciences at SU's Tygerberg Campus. The Department of Obstetrics and Gynaecology made substantial contributions to the maternal research agenda from 2001 and the Department of Internal Medicine to the adult research agenda from 2013.

FAM-CRU's activities align with the three University core activities namely: 1) Research, 2) Teaching and Training and 3) Service to community. A fourth core activity is transfer

of knowledge into policy, management and practice (through research).

VISION

A world where infectious diseases are easily managed and prevented within families.

4. MISSION

To improve the health of children and their families through research and innovation in infectious diseases.

5. CORE ACTIVITIES

5.1. Research

FAM-CRU's main focus is the conduct of prospective clinical studies. These include innovative clinical trials of treatment strategies for HIV and TB co-infection, pharmacokinetic studies and cohort studies for natural history determination. Vaccine studies include those to prevent TB and other bacterial and viral infections and also as therapeutic interventions. These studies may be self-initiated, or through clinical trial networks. For the latter, FAM-CRU investigators may contribute to the design of studies in various capacities (chair, co-chair, investigator or sub-investigator). FAM-CRU investigators may also undertake database explorations and address emerging questions from clinical trials, once the primary objectives have been addressed and after obtaining the relevant permission from sponsors, ethics committees and relevant regulatory bodies. Studies sponsored by pharmaceutical and vaccine companies are also undertaken, provided relevant to FAM-CRU's overall mission.

There is a wide mix of areas of expertise among senior scientific lead investigators for infectious diseases in the following groups of patients:

5.1.1. Infants and children, including premature, low birth weight

5.1.2. Pregnancy

5.1.3. Adolescence

5.1.4. Adults

There is expertise in following domains:

- 5.1.5. Clinical infectious diseases
- 5.1.6. Infection prevention and control
- 5.1.7. Neurocognition
- 5.1.8. Non-communicable diseases
- 5.1.9. Pharmacokinetics
- 5.1.10. Immunology
- 5.1.11. Virology
- 5.1.12. Microbiology

5.2. Teaching and Training

Teaching and training for the research teams are 'in service' and relevant to the studies undertaken. This consist of start-up meetings and updates around protocols. In addition, topics of general interest and specific for protocol team occupational classes are conducted regularly.

A wide spectrum of training and mentoring is undertaken by FAM-CRU including:

- 5.2.1. Researchers for Masters & PhD degrees (registered in the Department of Paediatrics and Child Health or other departments in the Faculty)
- 5.2.2. In service and protocol-specific training for the following team members:
 - Trial doctors
 - Project managers
 - Professional nurses
 - Staff nurses
 - Quality assurance officers
 - Counsellors
 - Data managers
 - Data entry officers
 - Regulatory officers
 - Pharmacists
 - Assistant pharmacists
 - Social worker
 - Counsellors
 - Field workers
 - Drivers
 - Cleaners
 - Clerks

5.3. Social Impact

Members of FAM-CRU render service on the following platforms:

- a) Clinical service in Tygerberg Children's Hospital
- b) Support to the community health service level and at primary health care facilities through offering 'state of the art' care and therapies unavailable to the community and through saving resources through performing routine and specialised assays
- c) Service to research community by serving on trial steering committees, endpoint review committees and data safety monitoring boards
- d) Service to general community through advisory committees at local, Provincial, National and Global level

5.4. Transfer of knowledge into policy and management

- a) Knowledge transfer to the scientific community and to policy makers through publications and conference presentations
- b) Dissemination of knowledge to communities where research takes place
- c) Communication of knowledge to the media
- d) Advocacy around issues pertinent to TB and HIV
- e) Participation in provincial, national and global guideline committees

6. PERSONNEL ESTABLISHMENT

The staff comprise the Director of FAM-CRU and such full-time or part-time staff which varies according to the specific research focus areas and studies at specific times. All staff will be appointed according to the policies and procedures of the University.

7. MANAGERIAL STRUCTURE

The FAM-CRU resorts within the Faculty's Department of Paediatrics and Child Health with collaboration with the Departments of Internal Medicine and Obstetrics and Gynaecology. The responsibility for advising on and approving the strategic management of FAM-CRU lies with its Governing Board and the responsibility for strategic and day-to-

day management lies with the Director, assisted by a Management Committee.

The decisions, functions and competencies of the Governing Board, Management Committee and Director, as outlined below, are subject to all institutional policies of the Faculty and University.

8. GOVERNING BOARD

The Governing Board will have the following composition, functions and procedures:

8.1 Composition

The Governing Board will consist of the following members:

- a) Deputy Dean: Research, Faculty of Medicine and Health Sciences or designee
- b) The Director of FAM-CRU
- c) The Executive Head of the Department of Paediatrics and Child Health or designee
- d) The Executive Head of Internal Medicine or designee
- e) The Executive Head of Obstetrics and Gynaecology or designee
- f) Between one and a maximum of four other staff members of the Faculty of Medicine and Health Sciences or other Faculty of the University, recommended by the Director, in consultation with the Heads of Department, to be appointed by the Dean of the Faculty of Medicine and Health Sciences on a rotational basis for 2 years at a time. Their replacement should be staggered in order to ensure continuity and corporate memory
- g) The Chair will be chosen from members of the Governing Board and excludes the executive Head of the Department of Paediatrics and Child Health, The Deputy-Dean: Research of the Faculty of Medicine and Health Sciences and the FAM-CRU Director. The term of office is 2 years, with the chair being eligible for re-election by the Governing Board.

In addition, the Governing Board has the right to co-opt no more than 3 representatives (both within and outside the University), on an *ad hoc* basis. *Ex officio* members of the Governing Board remain members of the Governing Board only as long as they retain office.

8.2 Mandate and Functions

The Governing Board is responsible for oversight of strategic management of FAM-CRU. This includes:

- 8.2.1** Evaluating and providing inputs into the strategic direction of FAM-CRU within its framework of the objectives
- 8.2.2** Evaluating, providing inputs and final approval of the business plan of FAM-CRU
- 8.2.3** Considering budget proposals, making recommendations regarding their feasibility and final approval of the budget of FAM-CRU

- 8.2.4** Determining the financial framework and processes of FAM-CRU in agreement with the University policies pertaining to this
- 8.2.5** Approving the annual financial statements and the report on the actual income and expenditure of FAM-CRU
- 8.2.6** Recommending the annual report of FAM-CRU to the Faculty Board for approval and communication with the Senate
- 8.2.7** Monitoring, evaluating and commenting on the performance of FAM-CRU with regards to its objectives
- 8.2.8** Assisting in the promotion of and lobbying for support for FAM-CRU to facilitate the achievement of the objectives
- 8.2.9** Giving attention to any other matters which might arise and which have bearing on FAM-CRU, or any matters where the Management Committee or the Director request guidance from the Governing Board
- 8.2.10** Delegating some of its functions to the Management Committee or Director, as deemed necessary.

9. MANAGEMENT COMMITTEE

A Management Committee with the following composition, functions and procedures does the scientific and strategic planning of FAM-CRU:

9.2.1. Composition

- a) The Director of FAM-CRU (convener and chair); if the director of FAM-CRU is also the Head of the Department of Paediatrics and Child Health, then another member should be co-opted in the management committee
- b) The Lead Investigators of FAM-CRU
- c) The Unit Manager
- d) The Committee can co-opt junior researchers as deemed necessary
- e) The Committee can consult content experts

9.2.2. Functions

The Management Committee shall be responsible for development of the strategic direction and scientific activities of FAM-CRU with regard to:

- a) The determination of strategic direction of FAM-CRU
- b) The development of research
- c) The identification of areas of funding
- d) The writing of proposals for funding
- e) Approval of the annual budget of FAM-CRU focusing on the scientific aspects
- f) Any other matters that may involve FAM-CRU and on which the Director of FAM-CRU requests guidance from time to time

10. RESEARCH, PUBLICATIONS, PATENTS AND INTELLECTUAL PROPERTY

- 12.1 FAM-CRU and the Department of Paediatrics and Child Health should be acknowledged in any publication emanating from research undertaken with the support of FAM-CRU. The Departments of Internal Medicine and Obstetrics and Gynecology will also be acknowledged for publications relevant to these disciplines.
- 12.2 Results of any research undertaken under the auspices of FAM-CRU may be published under the name(s) of the author(s), provided that adequate recognition is given to the role of FAM-CRU in the research.
- 12.3 InnovUS, the office for intellectual property of the University, will be consulted in all instances where intellectual property is concerned, including the pursuit of patent rights and the protection of intellectual property and all disputes and uncertainties involving intellectual property. University policies in relation to intellectual property will apply in all cases.