MeCRU CLINICAL RESEARCH UNIT

	SUBJECT	INFORMATION
1	**ABOUT THE DEPARTMENT (HISTORY/BACKGROUND)**	Mecru Clinical Research Unit (MeCRU) is a unit which was established at Sefako Makgatho Health Sciences University from October 2005. The facility was established with the support of MRC through the South African AIDS Vaccine Initiative (SAAVI) and was officially opened by Minister of Health, Dr Aaron Motsoaledi, on the 3rd of June 2010. It is located at the Sefako Makgatho Health Sciences University (SMU) where there is wide spectrum of qualified specialists in health who have varying degrees of competence in research and clinical work. The SMU is attached to Dr George Mukhari Academic Hospital, a 1400 bed tertiary hospital a tertiary hospital used for the training of health professionals. The Unit is administratively under the department of Microbiological pathology. It is managed by the leadership of a site principal investigator, supported by sub investigators, manager together with a board. The SMU also provides financial and human resource management support. An important element of the administration of the work of the Unit is the Community advisory groups (CAG) established to maintain a strong link between the Unit and the community. This gives credence to the belief that all research needs to be of benefit to the communities in which it is conducted.
2	**SERVICES RENDERED**	By design MeCRU was established to conduct clinical trials from phase II to IV. The Unit is built in such a way that it has capacity to run a number of studies concurrently. Being fully equipped

		with a licenced pharmacy, SANAS accredited laboratory and surrounded by a diversity of specialists in the medical field, the Unit is poised to support different clinical trials at different stages. The nature of clinical trials is such that access to the required numbers of participants for each study. To date MeCRU has proven to be able to access participants to the required level of participation and retain them. The core staff that provides the support for the management of the trials and community outreach and education has together many years of experience in running clinical trials. Participant access could be clinic based or large community based trials. As a Unit located in a university we have access to an ethic committee and where necessary a human subject protection committee is set up for additional administration and management of a trial. The ethics committee turnaround time has so far averaged three months but in some instances has been shorter. There is an appreciation of the need for speed and efficiency. The Unit is able to support all pre-trial based activities and in discussion with the sponsors or funders of the trial come to an agreement that will be mutually agreeable. The significance of the ability to collect good data cannot be overstated. The Unit has built capacity to both collect and present good data in clinical trials. Using data fax and electronic submission systems the Unit support the conduct of ethical and quality research. Quality control, query resolution, participant management and submitting reports timeously become the trademark of the unit. Where necessary continuous communication with the Ethics committee and other statutory bodies becomes part of the trial conduct. The MeCRU laboratory has the capacity to do PBMCs and store specimens with a state of the art tracking method. In addition it is equipped with a -80^{o}, -70^{o} and -20^{o} C freezers with a continuous temperature monitoring system.
3	**STAFF PROFILE (NAME,TITLE,CONTACT AND SHORT CV)**	Prof M Nchabeleng: Site principal investigator Maphoshane is a Microbiologist by training and has headed the department of Microbiology for the past 7 years. She has a keen interest in infection control and clinical trials. Her understanding of laboratory work and the intricacies of the science

		of healthcare positions the Unit in a place of advantage in the implementation and monitoring of clinical trials. She has over ten years of experience in conducting clinical trials. Dr MP Mathebula: Site sub-investigator Matsontso contributes many years of experience in public health and community engagement. He has worked in rural settings in community facilitation and development. His understanding of participant access and retention positions MeCRU in a comfortable place to conduct large studies. As a clinician himself he is able to be hands on in the conduct of clinical trials. MS Nontando Moeketsi: Site Project coordinator A manager with extensive laboratory experience and finance training. She has grown in the environment of clinical trials administration and management. Her ability to run a number of functions in a site the size of MeCRU has enabled the Unit to remain accountable to sponsors and staff. Nontando is able to inspire and lead teams to achieve against odds. **Current Personnel** MeCRU employs qualified personnel based on the project requirement to make sure that the project is a success. In the course of project implementation various types of support staff are employed in a project specific position to enable the Unit to complete the project **Key Personnel** **Principal Investigator (PI)** This is the person with whom the final responsibility for the Unit lies. All studies are managed by delegated PIs under the covering of the site PI. **Project Management** The Unit provides managerial support to PIs who are responsible for studies. Being in a tertiary

		institution with various specialists who have a clinical and teaching burden, running studies requires effective managerial support in order to be able to deliver on the studies. This service the unit provides for the benefit of the sponsors, participants and the PIs. **Socio Behavioural Scientist (SBS)** Many of the studies conducted at MeCRU have a socio-behavioural component. The Unit is able to provide the support necessary to conduct this aspect of the studies. **Medical Officers (MO)** They constitute the core staff at the Unit. By their nature clinical trials require that patients be examined and/or some medical aspect of engagement be conducted that requires a medical officer. Medical officers at MeCRU have Good clinical practice training and insurance to conduct clinical trials. **Study Coordinator (SC)** Regulatory compliance and the monitoring of studies are managed by the study coordinator(s). This roles is delegated to an experienced and competent person who also forms part of the core team at the Unit. **Quality Control Officer (QCO)** This role is one that is played by a competent officer with experience. It constitutes a critical part of the study and is closely monitored by the monitors from clinical trial monitoring organisations. This ensures that the studies produce quality data. **Community Liaison Officer (CLO)** The competence of MeCRU to mobilize and get community support constitutes a key element in the conduct of clinical trials. **Medical Laboratory Manager (MLM)** To run a certified laboratory with requirements that meet sponsor expectations and ensure accurate reporting of results and liaison with other laboratories MeCRU has as part of core staff a manager of the MeCRU laboratory.

		Research Pharmacist (RP) The MeCRU pharmacy is licenced as a pharmacy to handle both investigational product and medicines under the leadership of a pharmacist. Pharmacists are also employed as per trial requirement as project linked employees.
4	**Events Calendar**	N/A
5	**Community Outreach**	With the studies currently being MeCRU has continuous contact with communities to support their activities in the field and continue to educate them in the area of HIV and AIDS. A number of MeCRU staff do corporate social activities with the support of the Unit.
6	**Emergency Numbers**	**Professor Maphoshane Nchabeleng** **Tel: 012 521 5667**