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Gender differences in clinical and immunological outcomes in South African HIV-infected patients on HAART

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Standard Operating Procedure: Process to be followed for granting access to the Themba Lethu HIV/AIDS Comprehensive Care Management and Treatment and TB site for the purposes of research

Requests from individuals wanting to make use of the facilities at the Themba Lethu Clinic for the purposes of research must follow the following procedure and sign this document:

1. A written request must be sent to the Regulatory Manager at the Clinical HIV Research Unit, Department of Medicine, Helen Joseph Hospital (Marlene Naidoo; manaidoo@witshealth.co.za).
   1.1. The request should include:
      1.1.1. Names of individuals who will be conducting the research and their affiliations.
      1.1.2. Information on whether the research is for degree purposes and details of the institution that will grant the degree.
      1.1.3. A proposal detailing the objectives of the research, how the research will be conducted, methods of data collection and analysis and public distribution of results.
      1.1.4. A schedule indicating the proposed time-line for the start and duration of the study.
   1.2. The Regulatory Manager will communicate the requests to Dr Ian Sanne, researchers in the Clinical HIV Research Unit and the Head of the Themba Lethu Clinic.
      1.2.1. A copy of the proposal will be submitted to the Head of the Department of Medicine at Helen Joseph Hospital.

2. A consensus decision of the Clinical HIV Research Unit and the Department of Medicine at Helen Joseph Hospital on whether to grant access to the clinic will be required in all cases.
   2.1. The Regulatory Manager of the CHRU will ensure that the relevant documentation required by the Helen Joseph Hospital is completed and submitted to the office of the CEO of Helen Joseph Hospital for approval.
   2.2. Once permission has been agreed by the above groups, the decision will be communicated to the applicant by the Regulatory Manager of the CHRU.

3. By signing this SOP the applicant agrees to the following statements of assurance:
   3.1. All references to the data either in public verbal presentation or in print must credit the Clinical HIV Research Unit, Right to Care and the Department of Medicine at Helen Joseph Hospital.

3.2. Should the applicant wish to use the data for analysis beyond the originally submitted proposal, a further written request will be required and the procedures outlined above followed.

3.3. A final draft of the results of the research will be submitted to the CHRU for information and comment preferably before it is submitted for publication or public presentation.

3.4. The authorship of papers or presentations arising from the research will be decided using internationally recognized criteria, and must recognize the CHRU and Department of Medicine researchers appropriately, as well as any international researcher/s involved.

3.5. The applicant will also be required to submit a copy of the final product resulting from use of the data set to the Regulatory Manager at the CHRU and to the Head of the Department of Medicine at Helen Joseph Hospital.

3.6. The data derived from the study will not be shared, copied or provided to anyone other than the person/s outlined in the proposal.

4. Where the research involves the analysis of data in the Themba Lethu Clinical Cohort stored on TherapyEdge in addition to the clinical study outlined in 1 above, the requirements of the SOP "Process to be followed for granting access to data for research on the Themba Lethu Clinical Cohort and other Cohorts stored on the TherapyEdge database" shall be followed in addition to this SOP.

5. All research at Themba Lethu Clinic must have the formal written approval of the Human Research Ethics Committee (Medical) of the University of the Witwatersrand.

5.1. Copies of documents submitted for the purpose of obtaining approval from the above committee must be lodged with the Regulatory Manager at CHRU prior to the start of any study.

5.2. A copy of the formal approval of the protocol from the Human Research Ethics Committee (Medical) of the University of the Witwatersrand must be lodged with the Regulatory Manager at CHRU prior to the start of any study.

5.3. The applicant will be responsible for obtaining approval from any other authorities or Internal Review Boards as may be necessary.

6. If possible, the applicant should make an oral presentation to the Clinical HIV Research Unit at the start of the investigation and again once it has been concluded. This will be part of the regular academic programme of the Clinical HIV Research Unit.

7. A file will be maintained in the offices of the Clinical HIV Research Unit for all correspondence in this regard. In particular:
   7.1. Correspondence documenting the approval process as out lined above
   7.2. The signed agreement of the applicant (this SOP).
   7.3. A copy of the final product resulting from use of the data.

I have read and accept these conditions.

Applicant:

Date: 27/11/2007