



Level 1, Wernher Beit North Building, Faculty of Health Sciences  
Anzio Road, Observatory, Cape Town, South Africa

P O BOX 13801, MOWBRAY, 7705, Cape Town, South Africa  
(T) 27 021 406 6966 (F) 27 021 406 6255  
VAT No. 4750185565

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## **CLINICAL TRIALS UNIT (CTU) INTERNAL MONITOR 1 YEAR FIXED-TERM CONTRACT OBSERVATORY**

**The Desmond Tutu HIV Foundation (DTHF) is a registered non-profit organisation focused on the pursuit of excellence in research, treatment, training and prevention of HIV and related infections in Southern Africa.**

We have fantastic job opportunities across our businesses for talented people wanting to realize their full potential. Could that be you? If so, I invite you to explore the possibility of joining us to play your part in Desmond Tutu HIV Foundations' exciting future.

### **Main Purpose**

The function of this position will be to carry out aspects of quality assurance, including auditing study team compliance with required study procedures and Good Clinical Practice standards in order to verify that all research guidelines and regulations are adhered to.

### **Requirements:**

- Matric plus a documented qualification preferably in a Health related field
- 3 years' experience in working with complex multiple research studies
- Knowledge of Good Clinical Practice (GCP) guidelines and clinical trial site processes
- Computer literacy: MS Office, Microsoft Outlook
- Clinical trial operations expertise
- In depth understanding and knowledge of Division of AIDS (DAIDS) Networks and study data management would be an advantage
- Thorough understanding of Regulatory processes (HREC, MCC, NHREC, etc.)
- Excellent communication skills (English written and verbal)
- Sound technical knowledge and skills
- Strong client focus
- Excellent ability to build interpersonal relationships and partnerships
- Strong problem-solving and decision-making abilities
- Attention to detail
- Planning and organization abilities

### **Responsibilities:**

- Monitor adherence of Clinical Research Sites (CRSs) to data quality management plans.
- Report on effectiveness of Quality Management plans.
- Conduct 6 monthly reviews of the regulatory files.
- Ensure that all documents that require ethics and regulatory review are submitted timeously and have approvals in place.
- Ensure staff documentation is adequate and up to date.
- Ensure that necessary communications have been filed.
- Ensure that all regulatory progress reports are on file.

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PASSION | INNOVATION | PROGRESS

Association incorporated under Section 21 registration no. 1999/005072/08 : NPO no. 148-956  
Public Benefit no. 18/11/12/51

Directors: Prof R Wood; Prof L-G Bekker;

Ms Z Ebrahim(Chair); Ms T Tutu-Gxashe; Mr P Grant; Ms M K Ndebele; Mr C Abrahams; Dr M Sienaert

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- Ensure that all documentation is file according to ICH/GCP and sponsor requirements.
- Review regulatory trackers and give input for the design of regulatory trackers when needed.
- Ensure corrective action is implemented.
- Review QC and QA reports and monitoring reports to identify trends.
- Review CRS Bi-annual QA Reports and submit to DAIDS as per policy.
- Liaise with the CTU QA Manager, support and advise the PI, study team at sites in the conduct of QC and QA activities and policies.
- Conduct 6 monthly reviews of the regulatory files.
- Ensure that all documents that require ethics and regulatory review are submitted timeously and have approvals in place.

**Values fit: Passion Innovation Progress Integrity Respect Excellence**

To apply, quote Job reference, submit CV, motivation letter with certified copy of identity document and highest qualification; including details of three (3) current contactable referees to: Attention HR Manager [Jobs@hiv-research.org.za](mailto:Jobs@hiv-research.org.za) by 21<sup>st</sup> July 2017 Job reference: #DTHF/C087. Incomplete applications will not be considered. Only on-line applications submitted via our jobs portal will be considered.

*NB: Only short-listed candidates will be contacted. We are committed to equity in our employment practices. It is our intention to appoint individuals with the aim of meeting our equity objectives. We reserve the right not to appoint if no suitable candidates are identified.*

I understand and accept that, by applying for this role, I authorise Desmond Tutu HIV Foundation in its capacity as employer, to access my personal information stored, and to utilise said information for recruitment purposes for this role.

*This job may be removed before it expires.*

*If you have not heard from us within two weeks after the closing date please consider your application as unsuccessful.*

*Desmond Tutu HIV Foundation is a child friendly organisation committed to the protection of children.*

**For more information about the organization please visit our website at [www.desmondutuhivfoundation.org.za](http://www.desmondutuhivfoundation.org.za)**