Gidea Conradie (Ph.D.)

Current Location: South Africa **Phone:** +27 (0) 82 414 0166 **Email:** gidea_conradie@hotmail.com (Preferred method of contact)
Linkedin: https://www.linkedin.com/in/gideaconradie/

Clinical Research/Trials | Quality Control and Assurance Methodologies
Good Clinical Practice (GCP) Guidelines and Regulations

A seasoned professional offering extensive experience overseeing the long-term planning, oversight and evaluation of onsite quality management activities across medical research environments. Demonstrate expertise in successfully implementing quality assurance systems coupled with the ability to assess and identify needs within clinical trials. Leverage success in preparing units for audits and inspections while evaluating audit findings to implement the appropriate corrective and preventative actions required. Reputed for the ability to motivate and develop productive teams that will continually meet or exceed project objectives as well as improve quality and customer service.

Notable career highlights:

- **Ensuring that quality project deliverables comply with regulatory requirements.**
- **Successfully analysing potential issues and risks that affect the project, particularly those that affect more than one operational area.**

PROFESSIONAL WORK EXPERIENCE

John Hopkins University Contracted | Sep 2024 to present
Clinical Internal Monitor International and South Africa (Contract)

Tiervlei Trial Centre, The View,Tygervalley Health Centre Old Oak Road Tygervalley,Bellville, South Africa | May 2024 to Oct 2024.
Internal Quality Assurance Monitor (Part-time Contract)

- Performing ongoing reviews of active patient records and site files. Share findings with Site Coordinators and Investigators.

Desmond Tutu Health Foundation Gugulethu Research Office, Gugulethu Cape Town, South Africa | July 2023 to present.
Internal Quality Assurance Monitor (Part-time Contract)

- Successfully implementing quality assurance activities in the unit.
- Performing ongoing reviews of active patient records. Share findings with Site Coordinators and Investigators.

John Hopkins University Contracted by Aurum Institute, Remote | Aug 2020 to June 2023
Project Manager and Clinical Monitor Ethiopia and South Africa (Contract)

- Develop, maintain, and analyse study protocols and manual of operations.
- Ensuring standards are met as per principal investigators and research team.
- Educates and trains site and study staff in management of sponsored studies, including assurance of regulatory compliance.
- Assist in protocol, Informed Consent, and CRF design and review.
- Develops and demonstrates understanding of therapeutic area knowledge to assignments and project-related issues.

TASK: Improving Global Healthcare, Cape Town, South Africa | July 2020 to present December 2021
Clinical Research Monitor (Contract)

- Successfully implementing quality assurance activities of TASK-005_TB COMBO 01
- Performing ongoing reviews of all records of active patients and sharing findings with Site Coordinators and Investigators.
- Conduct Site Qualification, initiation visits, on-site monitoring visits, co-monitoring visits, and site closure visits of all phases of clinical trials Prepare site visit reports and assist site staff in resolving deficiencies.
- Conducting weekly internal monitoring by reviewing clinical records and case report forms. Preparing audits and inspections.
- Ensuring that consent forms, the screening and baseline visit and final visit are 100% checked and 10% of other visits checked before being returned to the Study Coordinators for corrections.

Desmond Tutu Health Foundation Gugulethu Research Office, Gugulethu Cape Town, South Africa | January 2020 to July 2021
Internal Clinical Research Associate (Contract)

- Successfully implementing quality assurance activities in the unit.
- Performing ongoing reviews of all records of active patients and sharing findings with Site Coordinators and Investigators.
- Conducting weekly internal monitoring by reviewing clinical records and case report forms.
- Ensuring that consent forms, the screening and baseline visit and final visit are 100% checked and 10% of other visits checked before being returned to the Study Coordinators for corrections.
- Preparing for audits and inspections.

UCT Lung Institute: Cape Town, South Africa | September 2015 to December 2019

Quality Assurance Manager/CRS Coordinator

- Overseeing the long-term planning, oversight and evaluation of quality management activities onsite.
- Planning and implementing the daily management of quality assurance activities and oversight of quality control activities.
- Successfully implementing quality assurance activities in the unit.
- Performing ongoing reviews of all records of active patients and sharing findings with Site Coordinators and Investigators.
- Conducting weekly internal monitoring by reviewing clinical records and case report forms.
- Ensuring that consent forms, the screening and baseline visit and final visit are 100% checked and 10% of other visits checked before returned to the Study Coordinator for corrections and then submitted to the Data Manager.
- Preparing for audits and inspections.
- Offering training to new employees on ICH GCP.
- Effectively coordinating site activities according to ACTG requirements.

Tygerberg Hospital, South Africa | February 2014 to August 2015

Operations Officer: Tread Research

- Overseeing and meeting daily onsite research activity objectives.
- Responsible for the quality control of all informed consents.
- Offering onsite training to employees on standard operating procedures (SOPs).
- Responsible for the quality control of all informed consents.
- Facilitating regulatory aspects as well as the international accreditation process at the Association for the Accreditation of Human Research Protection Programmes, Inc. (AAHRPP).

University of Stellenbosch: Tygerberg Campus, South Africa | September 2013 to January 2014

Project Coordinator of the HPTN 071 Study (Contract)

- Coordinating research processes.
- Ensuring that research objectives are met for the major HIV prevention study.

Helen Joseph Hospital, South Africa | January 2005 to June 2013

Quality Assurance Manager: Clinical HIV Research Unit - WITS Health Consortium

- Overseeing long-term planning, oversight and evaluation of onsite quality management activities.
- Managing daily quality assurance and oversight of quality control activities.
- Effectively implementing quality assurance activities in the unit.
- Conducting ongoing reviews of all records of active patients and sharing findings with Site Coordinators and Investigators.
- Directing weekly internal monitoring by reviewing clinical records and case report forms.
- Preparing units for audits and inspections.
- Training new employees regarding ICH GCP.
- Annual review, and if required, the writing of work practices in collaboration with Authors and previous reviewers.
- Overseeing the function of General Assistants in the unit.
- Facilitating patient finances.
- Acting as Occupational Health and Safety Representative.

EARLIER CAREER AND PROFESSIONAL WORK EXPERIENCE

Quintiles, Bloemfontein, South Africa | March 2004 to December 2004 - ***Project Manager: Data Management***

Quinta-Research, Bloemfontein, South Africa | April 2003 to February 2004 - ***Full-time Site Coordinator***

Quinta-Research, Bloemfontein, South Africa | March 2002 to March 2003 - ***Part-time Site Coordinator***

University of the Free State, South Africa | January 1996 to March 2003 - ***Researcher: Faculty of Health Sciences - Department of Paediatrics***

National Museum Bloemfontein, South Africa | September 1990 to November 1992 - ***Full-time Assistant Researcher: Department of Palaeontology***

University of the Free State, South Africa | February 1990 to September 1990 - ***Part-time Assistant Researcher: Department of Zoology***

STUDIES MONITORED (On request)

DATA MANAGEMENT STUDIES (On request)

CLINICAL RESEARCH STUDIES (On request)

CORE COMPETENCIES

- Clinical Research/Trials
- Quality Control and Assurance Methodologies
- Good Clinical Practice (GCP) Guidelines and Regulations **(Certificate 2024)**

- Human Subjects Research Biomedical Research 1 **(Certificate Jan 2025)**
- Quality Management Control Systems
- Audit Inspections
- Project Management and Implementation
- Data Collection Management and Analysis
- Team Motivation, Management and Development
- Onsite Research Activity Management
- Standard Operation Procedure (SOP) Implementation and Maintenance
- Customer Service
- Analytical Problem-solving
- Critical Thinking
- Report Writing and Analysis
- Decision-making Abilities
- Communication
- People Skills
- Sound Management Abilities
- Microsoft Office: Word, PowerPoint, Excel
- REDCap data system

PROFESSIONAL AFFILIATIONS

- Golden Key International Honour Society. 2008

EDUCATION

Certificate, Teaching and Technology Short Course 2022- ***University of Cape Town, South Africa***
Bachelor of Management Leadership (BML) 2009 - ***University of the Free State, South Africa***
Doctor of Philosophy (Ph.D.) in Zoology (Parasitology) 1983 - ***University of the Free State, South Africa***
Master of Science (M.Sc.) in Zoology (Histology) 1980 - ***University of the Free State, South Africa***
Business Psychology (Occasional Study) 1978 - ***University of the Free State, South Africa***
Statistics (Occasional Study) 1977 - ***University of the Free State, South Africa***
Higher Education Teachers Diploma 1976 - ***University of the Free State, South Africa***
Bachelor of Science (B.Sc.) Honours in Zoology 1975 - ***University of the Free State, South Africa***
Bachelor of Science (B.Sc.) in Zoology 1974 - ***University of the Free State, South Africa***
Matriculated: National Senior Certificate 1971 - ***Sentraal Secondary School, South Africa***

Excellent References on request