

Institution: Centre for Infectious Disease Research in Zambia (CIDRZ)
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LAB RESOURCES

Please describe the laboratory facilities available in your research institute, including the items listed below (if applicable):

<i>Lab space and equipment (general):</i>	Approximately 6000 sq meters with fully automated, semi-automated and manual testing equipment
<i>BSL-2 lab space and equipment:</i>	Approx 150 sq meters for TB Mycobacteriology
<i>BSL-3 lab space and equipment:</i>	Beckman Coulter FC500 X2
<i>Flow cytometry equipment:</i>	Beckman Coulter FC500 X2
<i>Other:</i>	BD FACScan X1

Please list the research groups in your institute, including the size and areas of expertise for each group:

- Haematology, Chemistry (general and immunochemistry), Flow Cytometry, Virology (viral load, HIV PCR from DBS), Serology, TB Mycobacteriology

BIOLOGICAL SPECIMEN REPOSITORY

Please describe the biological specimens stored at your institute:

- Plasma, Serum, Sputum, Stool, swabs, CVL
- Whole blood, Tissue

Does your institute have a database of stored samples: Yes



Please provide details on methods for biological specimen storage at your institute (e.g., are Standardized Operating Procedures used?):

- Study protocol mandated SOP adherence for specimen storage and shipment

Please describe the equipment/facilities available for sample storage at your institute, including items listed below (if applicable):

<i>-80C freezers</i>	6 upright units, two chest units
<i>Nitrogen storage tanks</i>	One generator carboy, 2 storage drier, 2 shipping containers
<i>Dry ice availability</i>	Yes, from South Africa
<i>Use of a nitrogen generator</i>	Yes, have a manufacturing plant

TRAINING AND EDUCATION

Please describe the training initiatives your institution has in place for individuals prior to working in clinical studies:

- All staff working on clinical studies complete online human subjects protection training before coming into contact with participants. Key staff, including investigators and study coordinators, complete online Good Clinical Practice training. All staff also receive local protocol-specific training, including informed consent, source documentation, quality assurance, adverse event reporting and management, etc.

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What rank are the majority of your trainees? (e.g., approximate numbers of undergraduate students, Masters, PhD, post-doc, MDs)

- We have several training programs, each targeting different cadres of health professionals. Through the Vanderbilt-CIDRZ AIDS International Training and Research Program, for example, we have provided funding for over 32 Zambian

physicians to receive Masters or PhD-level degrees. Through our HIVCorps public health fellowship, we have targeted medical students and recent MPH graduates. For the Fogarty International Clinical Research Scholars and Fellows programs, trainees are graduate students, residents, and clinical fellows. Most recently, the Zambian Cervical Cancer Research Capacity Initiative, an NCI-funded training program, is providing clinical and translations research training for 6 Zambian physicians or lab scientists in the specialty areas of epidemiology, gynecologic oncology, nutrition science, pathology, radiation oncology, and virology.

Do you offer training classes/courses for any of the following?

<i>Grant Writing</i>	Yes
<i>Manuscript/abstract writing</i>	Yes
<i>Computer skills, excel, prism, endnote, word, powerpoint</i>	
<i>Presentation skills</i>	Yes
<i>Epidemiology</i>	Yes
<i>Biostatistics</i>	Yes

Does your institute receive funds to support training initiatives? Yes

Please provide details about the funds your institute receive to support training initiatives:

AIDS International Training and Research Program (Fogarty International Center), Fogarty International Clinical Research Scholars and Fellows Program (Fogarty International Center), Cervical Cancer Research Capacity Initiative (National Cancer Institute), HIVCorps Public Health Fellowship (various programs).

Does your institution send trainees abroad for additional training? Yes

Please indicate the number of trainees sent abroad per year, the source of funding, the location of training, and the type of training received:

- Currently, 6 research scholars selected to participate in the Cervical Cancer Research Capacity Initiative (funded through the National Cancer Institute) are completing a 1-year research training program at UAB.

What Masters and/or Doctoral programs does your institution offer? None

COLLABORATIONS

Please list and briefly describe your current collaboration with any African institutions for either research or training purposes:

- Locally, we collaborate with the University of Zambia and the Zambian Ministry of Health in many of our training and research initiatives. We have also worked with the University of Cape Town (South Africa), Programme PAC-CI (Cote d'Ivoire), Cameroon Baptist Health Convention Health Board (Cameroon) as part of the multi-country PEARL PMTCT evaluation. As part of the leDEA-Southern Africa collaboration, we are part of a network of African cohorts that spans the region.

Please list and briefly describe your institution's collaborations and/or partnerships with entities outside of Africa (e.g., organizations and networks in the USA, Europe, etc. – including CFARS, NIH clinical trials networks, HPTN, HVTN, AMC, leDEA, USAID, PEPFAR, etc.):

- CIDRZ has a dedicated Clinical Trials Unit in Zambia affiliated with the ACTG, HPTN, MTN, and IMPAACT networks. We have ongoing collaborations with the University of North Carolina at Chapel Hill, the University of Alabama at Birmingham, Vanderbilt University, and Columbia University.

CLINICAL COHORTS

Do you have access to existing clinical cohorts in Africa or USA? Yes

Please describe each existing clinical cohort that you have access to, including specifics like “HIV-TB infected HAART naïve adults”, sample size, sample type, sex, age, and whether clinical samples are currently being collected and/or stored (specify which samples).

- MTCT Plus – 750 HIV infected women, their children, and partners; stored samples
- Pearl – 6790 cord blood samples collected from HIV exposed infants; stored samples
- CDCRx – 509 NVP exposed and unexposed adult women receiving NNRTI-containing HART

Are you planning to establish any new clinical cohorts over the next 5 years?
Yes

Please describe the clinical cohorts that you are planning to establish, including specifics such as “HIV-TB infected HAART naïve adults”, sample type, sex, and age:

- TB cohort – 400 HIV infected adult men and women newly enrolled in the HIV treatment program screened for prevalence and 1-year incidence of TB

- Antenatal screening – 200 HIV infected pregnant women receiving enhanced antenatal screening

DATA MANAGEMENT

Please describe the DATA MANAGEMENT FACILITIES available in research institute, including the items listed below (if applicable):

Data management expertise, including staff complement (general):

- On-site masters level data analysts oversee the team data manager and data entry technicians

On-site database design, implementation and trouble-shooting:

- An on-site database developer is responsible for development, implementation, and trouble-shooting

BIOSTATISTICAL SUPPORT

Please describe the BIOSTATISTICAL SUPPORT available in your research institute, including the items listed below (if applicable):

Biostatistical expertise, including staff complement/composition of PhD and Masters level biostatisticians:

- One PhD statistician and two Masters-level analysts perform data analyses in consultation with the research team