UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

Human Research Ethics Committee: (Medical)
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To Whom It May Concern,

RE: WITS HREC (MEDICAL) DIRECTIVE ON FUTURE BIOMEDICAL RESEARCH AND GENETIC TESTING

At the Human Research Ethics Committee: (Medical) meeting held on 28 January 2022, the committee re-confirmed its requirements regarding Future Biomedical Research and Genetic Testing, as per the Wits SOP on transport and storage of samples:

In accordance with the Department of Health, Ethics in Health Research, Second Edition, 2015: Section 3.3.6 Informed Consent

iii. Broad consent: the donor permits use of specimens for current research, and may also permit specimen storage for possible future research purposes, even though the precise nature of future research may be unclear at present. The nature of the further usage should be described as fully as possible **and should stipulate that further prior ethics review of the new study by the Wits HREC (medical) is necessary**. Permission may be sought to re-contact the person if intended future use is outside the scope of the current consent.

RECs should also bear in mind the vision of the H3Africa Initiative and its recommendation that consent should be 'broad enough to allow for future and secondary uses of data, in line with the opportunities to use such data in advancing knowledge to improve health. The consent processes need to be appropriate for the cultural contexts in which the research takes place and tailored accordingly'.

RECs should be aware that **'blanket' or unrestricted consent is not recommended** for the reason that it becomes difficult to implement and sustain fundamental ethical principles especially that of respect for persons. In South Africa's multicultural society, different views prevail about the use of biological materials. RECs should bear in mind that careful deliberation is always necessary when considering future use of materials. One reason is that biological materials cannot be completely anonymised. The presence of hereditary elements implies that any sample can be re-identified, albeit only to a group rather than an individual. This has implications for the consent process insofar as participants should understand clearly what is being requested.

In view of the above, for Future Biological Research and Genetic Testing:

- The University of the Witwatersrand, Human Research Ethics Committee: (Medical) will not approve open-ended, unspecified future testing on stored samples.
- The Wits SOP statement must be included in storage consent forms and/or genetic testing consent forms, confirming that any future research will first be reviewed, and approval sought from the Wits HREC (Medical).
- Future research must be within the scope/area of the disease initially being studied.
- Once details of additional tests are known, a letter requesting approval from the Wits HREC (Medical) should be sent to the Chairs of that Committee. This will be an expedited review, provided all the requirements of the SOP are met.
- POPIA will not approve Whole Human Genome Sequencing. The Wits HREC does not approve Whole Human Genome Sequencing.

University of the Witwatersrand, Human Research Ethics Committee: (Medical)