SAHPRA South African Health Products Regulatory Authority

NATIONAL HEALTH RESEARCH ETHICS COUNCIL

COMMUNICATION TO STAKEHOLDERS

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CLINICAL TRIALS CONDUCT – USA GOVERNMENT FUNDING PAUSE/STOP

This communication is issued in view of the current uncertainty in relation to USA Government funding for healthcare in South Africa, particularly in clinical research, and it intends to emphasise the responsibilities of various stakeholders in Clinical Trials.

The role of the South African Health Products Regulatory Authority (SAHPRA) is to protect the participants by ensuring that the clinical trials approved are scientifically sound and the conduct of Clinical Trials is in line with Good Clinical Practice (GCP) guidelines, especially the South African Good Clinical Practice: Clinical Trial Guidelines (SAGCP, 2020). Furthermore, SAHPRA ensures that the benefit of taking part in a clinical trial for participants outweighs the risk.

The National Health Research Ethics Committee's (NHREC) functions include to register and audit research ethics committees (RECs) reviewing health research and to set norms and standards for conducting research in humans and animals, including clinical trials. According to the guidelines of the NHREC, it is required that RECs have procedures in place for the monitoring of approved studies, including all clinical trials.

NHREC and SAHPRA would like to urge that Investigators, especially Principal Investigators, Applicants and Sponsors assess the impact of the pause or termination of funding on the feasibility of conducting clinical trials that have been approved by SAHPRA and the respective Ethics Committees. Every effort should be made to ensure that all the participants already included on the trial are protected, and their safety and care is not compromised in any way.

In accordance with the SAGCP, the participants, SAHPRA and the Research Ethics Committees should be immediately informed in case of any pause, early termination or if the study concludes. Section 5.1.3 of SAGCP (2020) Clinical Trial Guidelines states that in case a clinical trial is prematurely terminated or suspended for any reason, the Investigator must promptly inform the participants and must ensure appropriate therapies and

follow-ups are continued. Likewise, the National Department of Health (NDoH) guidelines on Ethics in Health Research (2024) highlight the need for RECs to monitor approved studies (Section 5.5.1.12 Monitoring).

NHREC and SAHPRA would also like to point out that as the participants are being informed of the impact of the loss of funding, resulting in study pause or termination, appropriate counselling of the participants should be immediately instituted.

Sites as well as National Principal Investigators are responsible for the clinical oversight of their study(ies) and must report adverse events, especially serious adverse events, or any other safety concerns observed in their clinical trials to both the Regulatory Authority and the Research Ethics Committee.

In the interest of the safety and well-being of clinical trial participants, the risk of interrupting or stopping the administration of investigational product (IP) should be considered and mitigated. Investigators should seriously consider not enrolling new participants on affected clinical trials or pause recruitment, consider alternative available treatment(s) for trial participants, and/or refer participants to standard of care or best possible alternative(s) available. Principal investigators should provide a clear plan of action of how serious adverse events will be managed, including agreements put in place with local health facilities, for the management of these cases.

Please remember that participant safety and well-being is essential and takes precedence over all other considerations.

SAHPRA and NHREC would like to emphasise that National Principal investigators should report any pause, termination or changes to approved Clinical Trials (including updating the South African National Clinical Trials Registry – SANCTR).

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