IMPAACT Specimen and Data Usage Agreement

For **Data Request (DR) 836**, entitled **"Individual Participant Data meta-analysis to quantify the impact of high ambient temperatures on maternal and child health in Africa"** a request has been made by **Matthew Chersich** [Proposing Investigator] of the **Wits Reproductive Health & HIV Institute, a Division of Wits Health Consortium (Pty) Ltd** for data and / or specimens (collectively, "research material") obtained under **PROMISE 1077BF** to be shared with **Matthew Chersich** [Recipient] of the **Wits Health Consortium (Pty) Ltd** [Recipient's Institution] for purposes of the National Institutes of Health (NIH) funded Project titled "Developing Data Science Solutions to Mitigate the Health Impacts of Climate Change in Africa: the HE2AT Center" ("research project") .

RECIPIENTS hereby acknowledge that the conditions for use of this research material are governed by the policies and procedures of the IMPAACT as can be found at https://www.impaactnetwork.org/sites/default/files/2023-01/FINAL_15_Ancillary_V4.0_20JAN2023.pdf. by the Institutional Review Board (IRB) or Ethics Committee (EC) at the PROPOSING INVESTIGATOR's INSTITUTION, and by the IRBs of the IMPAACT's specimen repositories, in accordance with the U.S. Department of Health and Human Services regulations at 45 CFR 46.

RECIPIENTS agree to comply fully with all such conditions and to report promptly to IMPAACT, and to the IRB or EC at the PROPOSING INVESTIGATOR's INSTITUTION, any proposed changes in the research project and any unanticipated problems involving risks to participants or others.

RECIPIENTS will not perform analyses on the research material beyond what has been approved by the IMPAACT leadership and by the IRB or EC at the PROPOSING INVESTIGATOR's INSTITUTION, and will not provide these data to any other party other than the research project's collaborating institution unless approved by IMPAACT and by the IRB or EC at the PROPOSING INVESTIGATOR's INSTITUTION. RECIPIENT agrees that all draft abstracts and manuscripts will be provided to the IMPAACT Publications Committee and funding agencies prior to submission to any journal or conference, with adequate time to review prior to submission, as defined in the IMPAACT Publications SOP which can be found at https://www.impaactnetwork.org/sites/default/files/2023-01/FINAL_19_Publications_V4.0_20JAN2023.pdf.

Any additional use of the research material beyond the research project requires prior review and approval by the IMPAACT and by the IRB at the PROPOSING INVESTIGATOR's INSTITUTION, which must be convened under an Office for Human Research Protections (OHRP) approved Assurance, where applicable.

RECIPIENTS will neither sell the research material nor use the research material for commercial purposes.

RECIPIENTS will take no action, either directly or indirectly, that could allow the identity of clinical trials participants who provided any of the research material to become known to RECIPIENT or to any other individual.

If this Usage Agreement involves human genotyping on DNA collected under an IMPAACT protocol:

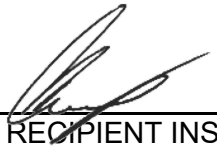
- RECIPIENT will submit to the IMPAACT Data Management Center in a timely manner all genetic assay data that RECIPIENT generates using these samples.
- If RECIPIENT receives IMPAACT clinical trials data, and then links these data (outside the IMPAACT Data Management Center) with human genetic assay data to perform statistical analyses, RECIPIENT agrees to destroy the clinical trials data after planned statistical analyses are completed. (NOTE: It is possible that a copy of these data will still exist on computer back-ups).

If this Usage Agreement does not involve human genotyping on DNA collected under an IMPAACT protocol:

- RECIPIENT will submit to the IMPAACT Data Management Center in a timely manner all assay data that RECIPIENT generates using these samples.

RECIPIENT agrees to comply with all applicable Country, State, or local laws or regulations and institutional policies which provide additional protections for human participants.

If RECIPIENT violates this Usage Agreement, the IMPAACT's response may include punitive action as determined by the IMPAACT Management Oversight Group and reporting to funding and regulatory agencies or entities as applicable.

	2 May 2023
Signature of RECIPIENT INSTITUTION	Date
Jéan du Randt	Chief Financial Officer
RECIPIENT's printed or typed name	RECIPIENT's Title
	2 May 2023
Signature of RECIPIENT INVESTIGATOR Professor Matthew Chersich	Date