# Response to Clarification Points for Data Sharing Agreement

## Definition of Limited Data:

***Original Clause RP1 :*** *The Data Provider will transfer a Limited Data Set to the Data Recipient. A “Limited Data Set” consists of health information that has had all direct identifiers concerning the subject of the record (and his or her employer, family, and household members) deleted; that is, the information excludes all of the following: names; street addresses (excluding suburb, small area or town); telephone numbers; fax numbers; electronic mail addresses; government insurance numbers; medical record numbers; health plan beneficiary numbers; account numbers; certificate/license numbers; vehicle identifiers and serial numbers, including license plate numbers; device identifiers and serial numbers; web universal resource locators (URLs); internet protocol (IP) address numbers; biometric identifiers, including finger and voice prints; and full-face photographic images and any comparable images.*

***Original Clause RP2:*** *The Data Provider will transfer a Limited Data Set to the Data Recipient. A “Limited Data Set” consists of health information that has had all direct identifiers concerning the subject of the record (and his or her employer, family, and household members) deleted; that is, the information excludes all of the following: names; telephone numbers; fax numbers; electronic mail addresses; government insurance numbers; medical record numbers; health plan beneficiary numbers; account numbers; certificate/license numbers; vehicle identifiers and serial numbers, including license plate numbers; device identifiers and serial numbers; web universal resource locators (URLs); internet protocol (IP) address numbers; biometric identifiers, including finger and voice prints; and full-face photographic images and any comparable images.* ***Given the nature of our research, we request that street addresses are not deleted, but are transferred as per the data transfer protocols of the study.***

***Suggested Revision for RP1:*** *The Data Provider will transfer a Limited Data Set to the Data Recipient. A “Limited Data Set” consists of de-identified health information, including essential variables such as unique IDs (study ID and participant ID), date of delivery or date of follow-up for maternal outcomes, and location information at a minimum level of city or town. The Limited Data Set excludes all direct identifiers such as names, street addresses, telephone numbers, email addresses, government insurance numbers, medical record numbers, and other identifying information as specified in the original clause. The purpose of the Limited Data Set is to ensure the privacy and confidentiality of the data subjects while allowing for the analysis of maternal and child health outcomes as described in the Annexes of this agreement.*

***Suggested Revision for RP2:*** Remains unchanged

## Definition of Study Data:

**Relevant Text:** "Study Data" shall mean data and results produced in the execution of the Study.

Question for Este and Donrich: Does the term "Study Data" encompass both raw data as defined above and processed results? How does this align with the NIH grant funding policy, which states that study data resulting from analysis of the data, where no personally identifiable data is included, will be made openly available through open data access platforms to support further research? What limitations or specifications should be applied to what can be made available, considering only aggregated data or fully de-identified harmonised data will be shared?

## Duration of Data Retention:

**Relevant text:**

* *Clause 2.1: This Agreement shall commence on the Commencement Date and will terminate on 30 June 2026 or upon completion of the Project, whichever event occurs first.*
* *Clause 2.2: Notwithstanding the abovementioned, either Party may cancel this Agreement with 30 (thirty) days’ prior written notice. On termination of this Agreement, the Data Recipient will immediately discontinue use of the Data and will return all copies of the same to the Data Provider or alternatively, and on the Data Provider’s written instruction, destroy all copies of the Data. The Data Provider, however, acknowledges that in order to maintain the integrity of results from the Project, the ability to amend, restrict, or delete Data disclosed to the Data Recipient may be limited, in accordance with applicable regulations.*
* *Clause 2.14: The Data Recipient will retain a copy of the Data for a period of 5 years after the termination of the over-arching NIH grant agreement (current Project End Date 30 June 2026) for the purposes of concluding and correcting any analysis and publications resulting from the Data. Any retention of Data after this 5-year period will be negotiated with the Data Provider.*
* *Clause 2.15: By signing this Agreement, the Data Provider confirms that it has the authority to transfer the Data and consent to provide the Data to the Recipient for use for the duration of this Agreement and as provided for in Clause 2.14.*

***Question for Este:*** *How does the duration of data retention relate to the transformation of data into the property of the HE2AT Center, and how does this affect the retention of raw data versus harmonized de-identified data? The clause 2.15 and 2.1 appear to contradict each other?*

## Inclusion of CHEAQI in HEAT Center:

**Relevant text:**

* *Clause 2.7:* Data Recipient will use the Data only for purposes of the Project. If the Data Recipient seeks to use Data for other purposes, the Data Recipient will obtain written consent from Data Provider, either by an amendment to this Agreement or a new agreement, before such use.

***Question for WHC Contracts department:*** Does the CHEAQI project(sub-study) fall under the umbrella of the HEAT Center as defined in the agreement?

## Permissions Required by Data Providers:

*Relevant Clauses:*

* *Clause 2.5: Data Provider retains ownership of the Data and retains all rights to distribute the Data to other third parties. Data Provider warrants its authority and that it has obtained the necessary consent required to provide the Data to the Data Recipient.*
* *Clause 2.10: The Parties acknowledge their obligation(s) to comply with Data Protection Legislation and that violation of the Data Protection Legislation may subject them to applicable legal penalties.*
* *Clause 2.15: By signing this Agreement, the Data Provider confirms that it has the authority to transfer the Data and consent to provide the Data to the Recipient for use for the duration of this Agreement and as provided for in Clause 2.14.*
* *Clause 4: Each Party will comply with Data Protection Legislation in relation to the performance of its obligations under this Agreement.*
* *Confirmation: The current text adequately covers the ethical and legal responsibilities of the data provider, with no need for alterations.*

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## Transfer of Data from SA to Zim/UPGC:

*Relevant Clauses:*

* *Clause 7: In the event that it is necessary for the Data Recipient to transfer Personal Data across national borders to authorised Collaborator/s or other authorized third parties (as may be agreed between the Parties), the Party providing the Data will ensure the lawful export of the Personal Data and shall enter into a separate agreement governing such transfer on terms no less stringent than the terms set out herein.*
* *Clause 7.2: In the event that the Data is transferred to a jurisdiction where POPIA does not apply, the respective Party transferring the Data undertakes that the Data will only be transferred to a jurisdiction with adequate protection as set out under Section 72 (1) of POPIA.*

*Question for Donrich in the ELSI: How do these clauses apply to the transfer of data from South Africa to Zimbabwe/UPGC, especially in the context of cross-border data transfers and compliance with POPIA and other relevant national legislation? Are there additional considerations or agreements required to ensure lawful and secure data transfer between these jurisdictions?*

## Data Impact Assessment and Logs:

* *Clause 11:* Records/Data Processing Register

*Clarification from Chris and Lisa:* What is the scope of the data protection impact assessment required under this clause, and are we currently fulfilling this requirement?

## List of Variables Requested:

* *Suggested Change:*

*The below list of variables is indicative and the final variable list to be finalised during discussion between the Data Provider and Recipient, based on data availability and relevance.*