HE2AT Centre Data Access Committee - ToR

# Preamble

The HE2AT Centre Data Access Committee (HCDAC) will review and approve or reject all requests from the research community for access to harmonized health data processed by the HE2AT Centre.

The Committee will evaluate whether the request conforms to HE2AT Centre data use policies and procedures, including consistency of the proposed research use with the informed consent under which the data were collected and any other limitations stipulated by the data providers.

Requests will only be considered for *harmonized and de-identified datasets* processed under the HE2AT Centre project. Requests for original source datasets will be referred back to the original data provider with consideration by the DAC.

# Composition of the Committee

HCDAC will be composed of 9 voting members with appropriate scientific, health ethics and data expertise

The committee members will include individuals who are:

(i) scientists involved in research relevant to HE2AT,

(ii) scientists with expertise in public health data, (iii) a data science expert, (iv) individuals knowledgeable in ethics of health research in Africa,

(v) person with legal expertise.

**They should not be members of the HE2AT Consortium and should have no conflict of interest with any of the HE2AT projects.** The HE2AT Steering Committee will consult broadly to identify appropriate members of the HE2AT DAC. Selection of members will be done by the HE2AT Steering Committee together with Funders.

The aim is that the majority of DAC members are people residing in Africa.

Terms of Appointment

The Chair shall be elected by a majority vote of the DAC members to a 3 year term which is renewable once. The start date of the first 3 year term will be set by the DAC.

Members will be appointed for a term of 3 years, with the possibility of serving a further three-year term. Rotation of members will be staggered to allow for continuity of membership; at least three committee members should remain on the committee while others are replaced.

## Scope of Work

The HE2AT DAC will review and approve or reject all requests from the research community (the "Research community" also includes members of commercial enterprises) for access to datasets. The DAC may request modifications to access requests before approval. If necessary, the DAC will delay a decision pending a request for additional information from the submitter.

The DAC must ensure that all requests conform with HE2AT policies and procedures including compliance with the terms of informed consent and any limitations stipulated by the submitting institution/investigators for each study.

Researchers who qualify to submit a request are defined as scientists or medical professionals employed at, or legitimately affiliated with academic, non-profit or government institutions, or commercial companies.

The HE2AT DAC will only consider requests for access to data submitted using the Data Access Request Form.

Submission of a Data Access Request (DAR) indicates that the Requesting Investigator (Requester) and his/her institution have agreed to the terms and conditions for data use specified in the Data Access Agreement (DAA) for the HE2AT Data Access Policy. This requires that Requesters, at a minimum,

agree to:

Abide by the agreed upon research uses of the requested dataset,

Not seek to identify individuals within the dataset,

Not distribute the data in any form to any entity or individual other than his/her research staff or trainees or independent collaborating investigators listed in the DAR under "Research & Related Senior/Key Person Profile"

Keep the data secure, and

Acknowledge HE2AT as appropriate in publications and presentations.

### Data availability requests

In instances where an investigator wishes to refer to availability and use of HE2AT data in research, prior to submission of a funding application, applicants may contact the HE2AT DAC to obtain information about data availability and access procedures to include in their research proposals, however, this by no means guarantees approval or availability at the time of eventual request. The DAC will only grant final approval for data sharing to appropriately reviewed funded applications.

### Monitoring and evaluation

The HE2AT DAC Secretariat will develop an annual report on the DAC activities which will be available to the ethics committees involved in the original approval of HE2AT research projects upon request. The report will include information on approved and rejected applications.

### Conflicts of Interest

Conflict of interest for DAC members includes, but is not limited to:

a. Collaboration on scientific publications with a Requester or a Co-Investigator listed on a data access request within three years of the submission date of the Request. In cases where the collaboration was on consortia-type publications, DAC will critically evaluate each case on its own merit.

b. Supervisory relationship with a Requestor or a Co-Investigator listed on a data access request

c. Being a Requester or a Co-Investigator on a data access request.

d. Business or financial connection to the requestor

DAC members are expected to review data access requests in advance to identify conflicts and communicate them to HE2AT ssecretariat staff. DAC members will recuse themselves from discussion and voting on requests for which they are in conflict. All conflicts of interest will be recorded in the minutes.

Operations

**Review schedule**

a. After submission of a DAR, HE2AT DAC Secretariat staff will use a standardized request review checklist (Appendix A) to determine whether applications are complete

b. HE2AT DAC Secretariat staff may ask for more information from the Requester and/or her/his institution if necessary.

c. HE2AT DAC Secretariat staff will post a summary of the request and completed checklist in a place accessible to the DAC only and ask members to review for Conflicts of Interest.

d. Once all actual and potential conflicts of interest are resolved, the full requests will be posted for all DAC members to review.

e. From an initial request, the HE2AT DAC will aim to reach and communicate a decision in 30-60 days.

**Quorum**

A quorum is defined as 5 out of 9 of the HE2AT DAC members.

If it is anticipated that a quorum will not be present for making decisions about requests at a DAC meeting, the meeting will be moved to a date such that a quorum is reached. Applications that have specific issues not covered by expertise on the Committee can be deferred for further consultation.

**Decisions about Data Access Requests**

Requests will be reviewed by HE2AT DAC members who can vote via e-mail or any other approved means to approve, reject, or discuss the request. Voting responses will be tracked by the Secretariat. If a quorum of HE2AT DAC members vote by the stated deadline and the vote to approve or reject a request is unanimous, the request can be approved/rejected without discussion at a DAC meeting and the requestor will be informed of the outcome. If the vote is not unanimous, the Chair will go with the consensus vote, and if there is no consensus then the majority vote should be accepted .

The DAC will aim to hold regular meetings in person, or via telephone or video conferencing software. If there is a disagreement that relates to an ethical matter, this should be referred to external ethics experts, and if agreement is still not reached it can be deferred to the original ethics committee(s) for the project. Other disagreements may be addressed by the project PI or the funder or by calling on external experts.

If an HE2AT DAC member is not able to attend a meeting at which a request will be discussed, the member can raise issues and vote via e-mail. If the HE2AT DAC member votes by e-mail prior to the meeting and important issues are raised at the meeting that may affect the member's vote, as judged by the members attending the meeting, the member who voted by e-mail will be informed of the discussion and given the opportunity to reconsider her/his vote and communicate this in writing to the DAC prior to a final decision. The DAC Chair will tally the in-meeting and e-mail votes, and this will constitute the final decision of the DAC on the matter.

The decision-making process will be reviewed by the HE2AT DAC members at least once a year to determine whether changes need to be made.

### Procedures for Checking Elements for Research Use

**Authentication and Terms of Access**

Applicants and their institutions are checked by the DAC Secretariat staff. To successfully submit a request, Requesters and their institutions must agree to the terms of access specified in the Data Access Agreement (DAA). Thus, authenticating Requesters and confirming agreement to the DAA require no further steps by the HE2AT DAC.

**Ethics approvals**

Ethics approval or a letter of exemption will be required for access to data, depending on the scope of the research. By agreeing to the terms of access in the DAC, Requesters and their institutions are certifying that any applicable National; U.S. Federal, State, and Local laws are being followed and that, if applicable, a Requester is in compliance with local human subjects’ protections. While the HE2AT DAC is not responsible for reviewing the ethics approval letter, it must be provided if required. If required, the DAC can seek the opinion of the original ethics committee that approved sample collection.

**Single institution application**

The Principal Investigator (applicant) must be a faculty member or government/private sector equivalent employed by the requesting institution. The Principal Investigator of the request and all collaborators listed as part of the request may be from the same institution. If they are not, then all participating institutions must be listed on the request form and HE2AT DAC staff will contact the Requester to explain to her/him that collaborators from different institutions will have to submit separate access agreements if access is granted.

Compliance with any data use limitations identified by the institutions that submitted the dataset(s):

The DAC members will review the research use statement provided by the Requester and information provided by the submitting institution, to determine whether the proposed research use is consistent with any data use limitations identified by the institutions that submitted the dataset(s).

**Decision feeback**

Any decision by the HE2AT DAC not to grant access will be conveyed to the Requester with feedback on the reasoning behind the determination, for instance, a brief summary of the points considered about the proposed use and how these were not consistent with the data use parameters for the dataset in question. All approved requests will be listed on the HE2AT website.

**Reconsideration of DAC decisions**

If a Requester wishes to contest the HE2AT DAC’s decision regarding the appropriateness of his or her access to data, the Requester may contact the HE2AT DAC Chair to discuss the issues or resubmit her/his request. The HE2AT DAC Chair may approach the HE2AT Steering Committee for their advice in problematic cases.

**DAC Annual Reports**

Annual Reports summarizing DAC activities will be generated by the HE2AT DAC Chair and will be due to the HE2AT Steering Committee.

Appendix A: Request Review Checklist

The HE2AT DAC Secretariat will review requests for data prior to submission to the DAC to ensure that all documents are present and in order. They will check the following:

* Is the HE2AT Data Access request form complete, correctly filled in and is the data access agreement completed and signed?
* Check evidence of scientific review and letter demonstrating institutional support
* Ensure that PI comments regarding future use or caveats are included, if so requested.

**The HE2AT DAC Secretariat will:**

* Using a standardized request review checklist, the HE2AT Secretariat staff will review requests to determine whether applications are complete prior to sending the request for a full HE2AT DAC review.
* All applications will be made to the secretariat who will firstly check that the request is complete and eligible for applying, secondly, they will manage the process of communication with the applicants on instruction from the DAC
* The secretariat will ensure the DAC receive all the documents required for making a decision, including:

1. Completed access request form
2. Ethics consent information for relevant project
3. Any additional conditions from relevant project
4. Information on timeline of any publication embargo
5. Availability of data being requested

* Maintain a list of applications and a spreadsheet documenting the process (with deliverable dates for each step of the process)
* Maintain a list of granted access requests on the HE2AT website
* Check publications from requesters to ensure acknowledgement is provided and relevant HE2AT publications are cited.
* Develop and circulate an annual report to the ethics committees involved in the original approval of HE2AT research projects on applications made for sample access, upon request. This will include both approved and rejected applications.