Data Sharing Policy

1. Overview

1.1. Sharing Research[1] data is a necessary component of Research, traditionally in the form of Publication[2] of findings in the scientific literature. The benefits of greater data sharing have been increasingly recognised as a mean of strengthening the utility[3,4] of Research, adhering to transparency recommendations and providing opportunities for additional Research. At the same time, there is a clear requirement to ensure that the rights and interests of Participants[5], investigators and other stakeholders are not compromised through data sharing practices, leading to the need for institutions to develop data sharing policies that are tailored to the types of Research data generated and the third parties with whom the data can be shared[6,7].

1.2. At Epicentre, we are fully committed to supporting international guiding principles on data sharing, including providing qualified research institutions access to anonymized or pseudonymized participant-level or aggregated data from Epicentre studies (including clinical trials, morbidity/mortality surveys, epidemiological interventions, etc.) to conduct legitimate scientific Research.

1.3. Epicentre is committed to strictly respect in all cases the medical confidentiality, the privacy and dignity of the Participants and their communities and comply with the General Data Protection Regulation 2016/679 dated 27 April 2016 and any other EU or Member State legislation, regulation, recommendation or opinion replacing, adding to or amending, extending, reconstituting or consolidating the EU General Data Protection Regulation (**GDPR**).

[1] "Research" means collecting information about a particular subject or research primarily and substantially aimed at understanding or treating a human disease or health condition.

[2] "Publication" means any abstracts, reports, external communication, websites, presentations or other peer-reviewed scientific publications that contain information, data or Results that are directly or indirectly related to the Data Set(s).

[3] Forms of utility include preventing unnecessary duplication of research, reducing the costs of answering new study questions and supporting the development of important forms of meta-analysis across studies.

[4] Pisani E, AbouZahr C. Sharing health data: good intentions are not enough. Bull World Health Organ. 2010; 88(6): 462-6.

[5] "Participant" means an individual from whom data and/or Human Samples that constitutes the Data Set(s) originate

[6] Holmes, J., Soualmia, L., & Séroussi, B. (2018). A 21st Century Embarrassment of Riches: The Balance Between Health Data Access, Usage, and Sharing. Yearbook of Medical Informatics, 27(01), 005–006. https://doi.org/10.1055/s-0038-1641213

[7] Pisani, E., Whitworth, J., Zaba, B., & Abou-Zahr, C. (2010). Time for fair trade in research data. The Lancet, 375(9716), 703–705. https://doi.org/10.1016/S0140-6736(09)61486-0

2. Key Principles

2.1. A fundamental responsibility of Epicentre is to protect and as far as possible not compromise the rights and interests of the Participants. The nature of informed consent provided by Participants is central to decisions on data and sample sharing and is strictly respected by Epicentre.

2.2. Given the global reach of many forms of data sharing and potential international inequities in resources available to support analysis and publishing, Epicentre reserves the prerogative to safeguard when necessary, the rights and interests of the researchers and research institution involved in the Research from which the Data Set(s)[8] are derived as primary beneficiaries of the Collection[9] This may include applying temporary embargos on data sharing and/or publishing to give priority to local participation, analysis and Publication of the Results[10] of the Research from which the Data Set(s) are derived.

2.3. The ownership or custodianship of the Data Set(s) collected by Epicentre's directors, officers, employees, agents, consultants or affiliated students (the **Representatives**) is held by Epicentre but delegated to the Principal Investigator, Coordinator or Director concerned by the Research for the duration of the Research. Exceptions occur where Epicentre's Representatives collect information as part of collaborations with other institutions or researchers, in which case ownership and custodianship is defined by the terms of the agreement underpinning this partnership.

2.4. Given the importance of balancing data sharing aims with protecting the rights and interests of Participants and researchers, requests of Requestor[11] to the Collection are made to Epicentre Data Sharing Committee (the **DSC**).

2.5. Data Set(s) from all studies in which Epicentre has ownership shall always be made available and sharable within the limitations described in this policy. The choice of including Data Set(s) in the Collection will be up to Epicentre, which will make any decision in the light of the principles set out in this policy.

[8] "Data Set(s)" means any single dataset or set of Human Samples (any material that comes from a person) with associated data, included in the Collection owned by Epicentre.

[9] "Collection" means the Data Set(s) with associated data owned by Epicentre, which may be shared by Epicentre with Requestors for Research.

[10] "Results" means the information, data, results, Intellectual Property generated in or arising out of the use of the Data Set.

[11] "Requestor" means an organisation (or it's Representative) seeking access to a specific Data Set(s). Once access has been granted following the process described in the present document, a Requestor becomes a "Data User".

3. Data Sharing Procedure

Data Sharing Committee

3.1. Data Set(s) sharing is overseen by the DSC. The DSC has two main roles: (i) advising on issues related to Data Set(s) sharing and (ii) making decisions on, or recommendations in response to specific Data Set(s) sharing requests. Its main objective is to work actively towards resolving issues that limit Data Set(s) sharing, while ensuring that the criteria and limitations listed throughout this policy and especially in Section 4 are taken into account.

3.2. Members of the DSC include the General Director of Epicentre (or their delegate), Directors of the Research and EIT (Epidemiology, Intervention, and Training) Departments, the Data Protection and Compliance Officer (**DPCO**), and an external member. Representative(s) from the study team of which Data Set(s) is proposed to be shared may also be asked to participate on an ad hoc basis. The DSC is chaired by the General Director and minutes are taken at each review by a designated secretary.

3.3. The DSC meets as required through face-to-face or email conferencing to make recommendations on requests for Data Set(s) sharing. The format of the DSC discussions will depend on the complexity of issues emerging from the request and the degree of consensus reached. The format for meetings will be proposed by the DSC chairperson. Face-to-face meetings will be held when email correspondence following requests do not lead to consensus. Meetings may also be face-to-face where significant resources are needed to make data available, or when stronger collaborative arrangements are needed to support Data Set(s) sharing. Decision-making within the DSC is through consensus.

3.4. The DSC meeting minutes shall include a summary of the final recommendations on data request applications. These shall be carefully stored following the appropriate procedures at Epicentre.

Data Sharing Requests

3.5. Applications by a Requestor are made to the DSC chairperson by email, using the access form. The form should be filled and signed by the Requestor when submitting the application. The following information is required from the Requestor: the Requestor details as stated in the request form, a description of the required Data Set(s), the (time-bound) objectives of the request, any known or perceived associated risks and a tentative overview of data analysis plan or a lay summary of the Research. The Requestor should submit a scanned application with an original signature.

3.6. The DSC chairperson will check with the DPCO if the requested Data Set(s) are available. If the Data Set(s) are not available, the DSC chairperson will communicate this information to the Requestor. If Data Set(s) are/can be made available, the request will be discussed by the DSC according to the procedure aforementioned.

3.7. Depending on the type of request, the objectives of the request, the sensitivity of the requested Data Set(s), the risks associated, the benefits to Participants and Epicentre, etc. the DSC might require that a suitable agreement be reached with the Requestor.

4. Criteria, Limitations and Conditions of Use

Criteria

4.1 Applications for use of Data Set(s) are limited by the terms under which informed consent were obtained from Participants, except in case of a waiver from the country(ies) where Data Set(s) have been collected or originate from (the **Host Country**) Ethics Committee or any other appropriate ethic committee.

4.2 In addition to the limitation described in 4.74.6, certain types of Data Set(s) are Sensitive Data[12] or Personal Data[13] and sharing of such Data Set(s) will be restricted. These include, but are not limited to, information on HIV status, sexual behaviour, ethnicity and potentially stigmatising conditions. All such Data Set(s) sharing requests will be carefully considered on a case by case basis to minimise any potential risks of harm to any individuals, community or institution related to the Data Set(s). If the requested Data Set(s) contains any Personal Data or Human Samples, or is subject to limits relative to the consent of the Participants, the Requestor, or Epicentre in some cases, shall seek and obtain ethics approval from the Host Countries Ethical Committees before any sharing of the requested Data Set(s) as well as any other ethics approvals needed to conduct the Research that will be carried out by the Requestor.

4.3 Data Set(s) can only be used for the purposes proposed in the application form, to the extent that the Data Set(s) is reasonably necessary to achieve the Research, as agreed in the agreement between Epicentre and the Data User (where applicable), and may not be used in such a way that damage or distress is or is reasonably likely to be caused to any Participants.

4.4 Priority in applications will be given to Requestors who are Representatives of Epicentre or Médecins Sans Frontières and their partners. Other research institutions and their Representatives who are willing to pursue the Research from which the Data Set(s) are derived in collaboration with Epicentre researchers or who have a satisfactory record of Publication in the field of the proposed Research are eligible but may be given lower priority.

4.5 There may be an embargo/fair use period in which Data Set(s) are not accessible to Requestors to allow the researchers and research institution involved in the Research from which the Data Set(s) are derived to complete the said planned Research. The period of time needed, and the reasons for this, will be decided by the DSC. The justification for any embargos used will be shared with Requestors, who may also submit an appeal to the DSC.

[12] "Sensitive Data" refers to any subset of information that can be voluntarily or involuntarily misused against the interests of a Participant and/or Epicentre activities or put the latter at risk for political reasons, financial gain or any other reasons.
[13] "Personal Data" are any subset of data or information that directly or indirectly identifies an individual. It includes data that reasonably could identify an individual. For example, it includes: (i) data that directly identifies individuals (name, ID number, household address or household GPS coordinates, biological samples, biometrics and all other techniques designed to directly identify individuals) and (ii) a combination of data that together can reasonably make it possible to identify an individual.

Limitations and Data Privacy

4.6. Data Set(s) will only be shared in a pseudonymised or anonymised form, without access to personal identifiers, including names, specialised roles and geographic identifiers.

4.7. Data Set(s) can only be disclosed to Data Users and cannot be transferred or disclosed in any part to any third party. Moreover, Data User shall not use or store the shared Data Set(s) at any facility outside of its control.

4.8. Data Users must agree not to attempt to link the Data Set(s) provided with any other data set without the prior permission of Epicentre.

4.9. Data Users must agree not to identify or contact any specific individual or groups of individuals or medical institutions from whom data or Human Samples are included in the Data Set(s).

4.10. Participants of Data Set(s) that include their Personal Data or Human Samples have the right to withdraw their consent to the use of such Data Set(s) and to request access to, to modify, to destroy or to retrieve such Personal Data or Human Samples. In such case, Data User will be required to take appropriate measures, at its own costs, to comply with the Participants requests and to inform Epicentre in writing that such measures have been taken.

4.11. Data Users are free to use these Data Set(s) in their Research from the point of release, under the conditions of the agreement between Epicentre and the Data User, but are asked to respect the interests of the researchers and research institution involved in the Research from which the Data Set(s) are derived in conducting the primary Research. Data Users shall discuss any overlapping uses with the primary researchers in advance. Where more than one primary researcher is involved, discussions on any overlapping interests shall be held.

Terms & Conditions of Use

4.1 Data Users may, after prior agreement of Epicentre, publish Results arising from their use of the Data Set(s) for the agreed purpose providing the Data Set(s) itself is not disclosed as well as any Sensitive Data or Personal Data and in strict accordance with the provisions of the agreement between Epicentre and the Data User. Aggregate or generic information generated from the Data Set(s) may be published on the provisos that: i) such aggregate or generic information does not allow Participants or groups of Participants to be identified with reasonable effort; ii) no damage or distress is or is reasonably likely to be caused to any Participants, groups of Participants or communities from which they are drawn; and iii) no attempt have been made to identify the Participants.

4.2 A copy of any Publication based on shared Data Set(s) from Epicentre should be sent to the Representative of the study team from which the Data Set(s) originates from and/or the DSC. Such Publications should include an acknowledgement using the text as follows: "*This paper/publication used data and/or biological samples provided by Epicentre in accordance with the informed consent of the participants from which the data and/or biological samples originate from and approved by the << the relevant ERB>>*".

4.3 Data Users are required to share with the DSC the Results of their use of this Data Set(s), including positive and negative outcomes.

4.4 Epicentre reserves the right to audit the Data User's use of the Data Set(s) if this is considered necessary. Data Users found to be in breach of the agreement between Epicentre and the Data User will be denied future access to Epicentre Data Set(s) and, if applicable, their institutions and funders will be informed.

4.5 The Data User may seek Intellectual Property[14] rights, or any other protection in respect of Results, with the prior written consent of Epicentre and provided that the Data User will do its best efforts to avoid prohibitively costly approaches, restrictive Intellectual Property strategies or any other issues that may inhibit or delay the use of the Results to the benefit of low and middle income countries.

4.6 The Data User shall comply with (i) any and all national, international or Host Countries laws, regulations, governmental rules or guidelines applicable to the use of the Data Set(s), (ii) best standards and rules relating to medical confidentiality, medical ethics and medical research and (iii) the GDPR and any and all national, international or Host Countries laws, regulations, governmental rules or guidelines applicable to the protection of the privacy and confidentiality of the Participants.

[14] "Intellectual Property" means any patentable inventions or any other proprietary rights that are conceived or reduced to practice by or on behalf of Data User, in connection with or by use of the Data Set(s) (hereafter "Inventions"), and (ii) any data, results, know-how, and other intellectual property that are not Inventions and that are generated by or on behalf of Data User, in connection with or by use of the Data Set(s) (hereafter "Know-How').