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MSF DATA SHARING POLICY

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DEFINITIONS

- ‘*Collection*’ denotes the datasets and the sets of Human Samples with associated data, which may be offered by MSF for Research to investigators. The Collection can be viewed on an online catalogue that is available at <http://fieldresearch.msf.org/msf/> and further information can be obtained from data.sharing@msf.org.
- ‘*MSF Dataset*’ means any single dataset or set of Human Samples with associated data, included in the Collection. An MSF Dataset may have been compiled:
 - (i) For a specific, focused Research, or
 - (ii) For health service provision or planning
- ‘*Custodian*’ means the organisation or committee, who has formal responsibility for a specific MSF Dataset at the time a request for access is received. The Custodian is accountable for maintaining the integrity and security of the MSF Dataset and for providing access under whatever sharing terms may be in place. The Custodian may or may not be MSF-Epicentre.
- ‘*Data Subject*’ means an individual from whom data and/or Human Samples that constitutes MSF Dataset(s) originate.
- ‘*Host Country*’ means the country(ies) where the requested MSF Dataset(s) has been collected or originates from.
- ‘*Host Country Ethics Committees*’ or ‘HCECs’ are the organs responsible for overseeing Research in Host Country(ies).
- ‘*Human Samples*’ or ‘*Human Biological Material*’ means any material that comes from a person (e.g. blood, body fluids, tissue Human Samples, microbiological isolates, urine, excrements, etc.).
- ‘*Intellectual Property*’ means any patentable inventions or any other proprietary rights that are conceived or reduced to practice by or on behalf of Recipient, in connection with or by use of the requested MSF Dataset(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 Recipient, in connection with or by use of the requested MSF Dataset(s) (hereafter “Know-How”).
- ‘*MoU*’ means Memorandum of Understanding.
- ‘*MSF*’ means any section of Médecins Sans Frontières or any MSF affiliate. Epicentre, an MSF affiliate, may be mentioned when particularly relevant.
- ‘*MSF DSC*’ shall mean MSF Data Sharing Committee.
- ‘*MSF ERB*’ means Médecins Sans Frontières Ethical Review Board. MSF ERB can be contacted at: MSFERB-Secretariat@msf.org
- ‘*MTA*’ refers to Material Transfer Agreement, which is an agreement by which MSF agrees to transfer a requested MSF Dataset to the Recipient.
- ‘*Operational Directorate*’ means an MSF entity involved in the direct provision of assistance to beneficiaries under the name of MSF;

- *'Personal Data'* refers to any subset of information, including demographic information that identifies an individual, directly or indirectly (or there is reasonable basis to believe that the information can be used to identify an individual), and in particular by combination with his name, identification number, location, contact details, GPS coordinates or one or more factors specific to his physical, physiological, mental, economic, cultural or social identity.
- *'Publication'* means any abstracts, reports, external communication, websites, presentations or other peer-reviewed scientific publication that contains information, data or Results that are directly or indirectly related to the requested MSF Dataset(s).
- *'Requestor'* means an organisation seeking access to a specific MSF Dataset. Once access has been granted following the process described in the present document and a MTA has been signed, a Requestor becomes a *'Recipient'*.
- *'Research'* means collecting information about a particular subject or research primarily and substantially aimed at understanding or treating a human disease or health condition. The definition is purposely very broad and includes notably, but not exclusively, what is commonly referred to as scientific research, operational research, epidemiology, clinical research, program research, evaluations, retrospective program analysis etc.
- *'Results'* means the information, data, results, Intellectual Property generated in or arising out of the use of the requested MSF Dataset(s).
- *'Sensitive Data'* refers to any subset of information that can be voluntarily or involuntarily misused against the interests of a Data Subject and/or MSF activities or put the latter at risk for political reasons, financial gain or any other reasons. Sensitive Data is further defined in article 1.1 of Part II of the present document.
- *'Third Party'* means any entity or person other than MSF and the Requestor/Recipient.
- *'Transfer'* is used in its most general sense to include any and all transfers of MSF Datasets (not only international transfers of Personal Data).

MSF POLICY STATEMENT

MSF, as an international medical humanitarian organisation, and Epicentre, its Research affiliate, place a high value on monitoring and documenting MSF medical interventions in order to continually improve the quality of care delivered. This results in a large amount of routinely collected data being produced. In addition, there exists an emphasis on Research particularly with neglected patient groups and on neglected diseases. There is also a clear recognition of the responsibility MSF carries to share and disseminate knowledge given that many of the populations MSF works with are neglected, and excluded from traditional sources of Research.

MSF's large repository of Research data together with routinely collected data can potentially be of value to researchers working in public health. MSF recognizes the ethical imperative it has to share its data openly, transparently and in a timely manner for the greater public health good. This imperative is particularly strong recognizing that MSF works with vulnerable and marginalized populations for whom there is often an insufficient evidence base to address their health needs.

Data sharing policy relies on good practices in data collection, use and management. Organizationally, there is commitment to further strengthening MSF standards in this area, particularly with respect to MSF legal and ethical obligations to its patients to collect, manage and protect their data responsibly. In addition, MSF will prioritize for its data, information technology solutions that facilitate data sharing.

This policy must be read together with the MSF policy on data protection. [Currently in draft form].

VISION

MSF, as an international medical humanitarian organization, and Epicentre, its Research affiliate, are committed to share and disseminate health data from their programs and Research in an open, timely and transparent manner in order to promote health benefits for populations while respecting ethical and legal obligations, notably towards MSF patients, Research participants and their communities.

SCOPE OF POLICY

This policy applies to all health data generated in MSF programs or sites, where MSF acts as a Custodian for such data. It includes but is not limited to data generated from: health information systems, patient records, surveillance activities, quality control activities, surveys, Research, patients/ Research Participants' Human Biological Material.

PRINCIPLES

MSF commits to promote greater access to and use of MSF health data in an ethical manner that respects the principles outlined below:

- **Medical confidentiality** is fully respected;
- **Privacy** and dignity of individuals and communities are not jeopardized;
- **Sensitive Data is protected.** The nature of MSF operations and target populations are such that data collected often involves highly Sensitive Data. Sensitive Data can include but is not limited to, data related to victims of violence and data which is potentially stigmatizing to individuals or groups. Data sharing shall be implemented

by MSF in a way that will not put at risk or be misused against the interests of MSF patients, Research participants, MSF employees and MSF organizations for political reasons, financial gain or any other reasons.

- **Equitable:** Any approach to sharing MSF Datasets should recognize and balance the needs of practitioners or researchers who generate and use health data, other analysts who may want to reuse such data and communities and funders who expect health benefits to arise from Research.
- **Promote health benefits to the greater population:** The aim of data sharing is to bring wider health benefit to individuals and communities outside of those in which the data was collected. Data to be shared must have the potential to lead to this benefit at either the population or patient level.
- **Local Benefit sharing:** Data sharing will prioritise data which are of benefit to the local communities where the data was collected, as well as to patients and communities similar to those in which MSF works, in particular marginalized or neglected populations. Notwithstanding this, there is a recognition that benefit sharing can be with a wider community of individuals, and will not always result in benefits to local community.
- **Intellectual Property and commercial use:** Recipients of MSF Datasets shall use their 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 of their Research to the benefit of low and middle-income countries. In particular, they shall do their best efforts to avoid anything that could seriously limit follow-up Research and/or development and/ or equitable and affordable access to potential final product(s) by end users in such countries. Recipients shall not seek any Intellectual Property rights of any kind in respect of Results generated or arising out of the use of MSF Datasets without prior written consent.
- **Collaborative partnership:** in line with MSF's Ethical Framework for Medical Research, Recipients of MSF Datasets will engage wherever possible with the local research community and the local community where the MSF Dataset originates from.
- **Efficient:** Any approach to data sharing should improve the quality and value of the delivery of health care, and increase its contribution to improving public health. Approaches should be proportionate and build on existing practice and reduce unnecessary duplication and competition.

POLICY STATEMENT

MSF is committed to work towards maximizing the availability of health data of wider interest to public health researchers with as few restrictions as possible.

To that extent, MSF will work towards creating a Collection of health data for inclusion in an online catalogue that respects the vision, principles and policy statements included in this policy.

1. MSF data sharing practices will comply with the various **international and national legal obligations** applicable, notably those relative to medical ethics, medical law, Research and privacy law.
2. The choice of MSF Dataset, including any Human Samples, for inclusion in the Collection will be based on the vision and principles outlined in this document.
3. MSF Researchers should consider their approach for managing and sharing data at the Research proposal stage. In cases where the proposed Research is likely to generate data outputs that will hold significant value as a resource for the wider public health community, MSF researchers should develop a written data management and sharing plan as early as possible, including the resources needed to carry out such plan. The inclusion of a broad consent in Research proposals will be considered where there is evidence of a clear potential for the greater public good and if risks are limited.
4. Access to MSF Dataset originating from Research must be fully consistent with the terms of consent under which it was gathered. Recognizing the existence of historical Research data sets of high potential benefit to patients that were created prior to this policy coming into effect, there will be rare occasions where data sets or human biological samples are shared outside of the original consent. In these exceptional cases, attempts should be made by MSF to return to study participants to expand the consent or failing that, request consent from the community where the study took place. Following this, ethical clearance from competent ethical authorities and of the MSF ERB must be secured.
5. In addition, Recipients, who wish to access any MSF Datasets that include Personal Data and/ or Human Samples, must secure ethical clearance from competent ethical authorities and of MSF ERB.
6. Secondary data users will respect the rights and obligations relative to MSF Datasets and its Custodian(s) and are expected to add value to the MSF Datasets they use. Researchers creating new data sets for secondary analysis from shared primary MSF Datasets are expected to share those new data sets and act with integrity. Publication of Results of secondary analyses in peer-reviewed journals is expected to be done in a manner consistent with MSF scientific publishing policy which promotes open access publishing; to that extent, the Recipient shall use its best efforts not to enter into any copyright agreement that unreasonably restricts

access in any way to electronic versions of any Publications, notably in light of potential public health benefits of releasing results immediately and without restrictions. It is understood that proper acknowledgement of the original researchers will be made.

7. Data sharing will normally take place through a Managed Access Procedure. Exceptions will be for publicly accessed MSF Dataset referred to in point 8. The Managed Access Procedure will allow for individualization to match the requested MSF Dataset, but will follow the general framework outlined in Part II. The Managed Access Procedure established should be proportionate to the risks associated with MSF Datasets, and must not unduly restrict or delay access.
8. There is an intention to work towards the placing certain MSF Datasets of importance to the public health research community on public repositories (e.g. Field Research) where possible and appropriate. This will require a separate procedure.
9. All data collection under the control or process of MSF will follow the guidance outlined in the MSF Data Protection Policy (currently in draft form).
10. Costs associated with the sharing of MSF Datasets (e.g. processing of applications, creation and maintenance of databases, ERB review) will be borne by Requestors.

MANAGED ACCESS PROCEDURE

1. *ELIGIBILITY FOR ACCESS*

1.1 Selection of data for the Collection (online catalogue)

All MSF data that falls under the scope of MSF Data Sharing Policy is eligible to be proposed for inclusion in the Collection. The decision to include specific data, datasets and/ or Human Samples will be made by the Medical Director(s) representing their own Operational Directorate(s) Custodian of such data, datasets and/ or Human Samples. Their decision will be guided by the vision and principles outlined in the Policy and should not be unreasonably withheld.

1.2 Limitations

1.2.1 Related to Sensitive Data

Sensitive Data means any subset of information that can be voluntarily or involuntarily misused against the interests of the Data Subject and/or MSF or even put the Data Subject and/or MSF employees and activities at risk for political reasons, financial gain or any other reasons. In determining eligibility of data sets for inclusion in the Collection, Medical Directors must take into account the potential sensitivity of data and ensure appropriate safeguards are in place in the managed access procedure. Should potential safeguards not be appropriate or sufficient, MSF may decide that such datasets will not be eligible for sharing and will therefore not be included in the Collection.

Examples of Data considered as Sensitive Data by MSF:

- (i) Any data from which an implication of criminal conduct could be drawn and/ or that can put Data Subjects at serious risk (including death); this includes data on violence-related medical activities particularly but not exclusively in contexts of conflicts: (1) any data related to violence – bullet wounds; and (2) any data related to sexual violence;*
- (ii) Data collected from MSF activities in prisons or any situation that can be assimilated to detention or deprivation of liberty (including certain refugees or displaced settings);*
- (iii) Certain data variables such as those that could indirectly imply, truly or not, racial or ethnic origin; political or religious opinions (for example from the origin or the location of the Data Subject);*
- (iv) Data related to sicknesses with an obligation to abide to treatment.*

Data potentially considered as Sensitive Data by MSF (non exhaustive):

- (i) Data that can put Data Subjects at risk of stigma, discrimination and even criminal sanction (including in certain countries or groups of population, HIV and TB data);*
- (ii) Data on sicknesses or epidemic outbreaks*

1.2.2 Limitation(s) resulting from contracts or MoUs

- (i) Access to certain MSF Datasets may be limited by contracts or MoUs signed by MSF or the Custodian with Third Party(ies).*

- (ii) Such contracts or MoUs may require that the decision regarding the sharing of the MSF Dataset should be taken with the approval of Third Party(ies).
- (iii) Whenever possible, limitation(s) shall be flagged on the online catalogue available at <http://fieldresearch.msf.org/msf/>

1.2.3 Limitation(s) by the scope of formal consent

- (i) Certain MSF Datasets may be limited by the scope of consent of Data Subjects, notably in case the proposed MSF Datasets was initially compiled for Research.
- (ii) Use of MSF Datasets beyond the scope of consent:

Requestors who wish to access such datasets must supply evidence that ethical approval has been granted by HCECs and MSF ERB; such approvals will take into account reasonable attempts made by MSF to return to study participants to expand the consent or failing that, to request consent from the community where the study took place.

1.3 Eligibility of the Requestor

Access to the Collection is limited to all appropriately qualified researchers¹ from academia, charitable organizations and private companies, such as drug companies.

2. APPLICATION FOR ACCESS

2.1 Information to be supplied by Requestors

Applications are welcome from researchers working in public health that are affiliated to a recognised Research institution, academia, charitable organisations and private companies, such as drug companies.

2.1.1 Applications for access to MSF Datasets offered on the online catalogue should be submitted to MSF via data.sharing@msf.org

2.1.2 Applications shall include:

- (i) Details of the Requestor:
 - Name,
 - Affiliation with institution/organisation,
 - Contact details,

¹ We define an appropriately qualified researcher either as someone who has authored a relevant peer reviewed article that we can locate on PubMed, and who is still working in the field.

- Research CV.

(ii) Details of the Research:

- Research outline,
- Proposed methodology,
- Funding sources
- Evidence for ethical approvals sought or that will be sought,
- Evidence of other approvals sought or that will be sought,
- Details of collaborators, sponsor, investigator(s) and institution(s) involved in the Research,
- Plans for Publication of results (including whether the Requestor will only seek open access Publication(s) or not),
- Lay summary of the Research.

(iii) Details of the MSF Dataset(s) requested:

- Reference number of the MSF Dataset(s) requested from the online catalogue;
- Conditions and timeframe for storage, and for return or destruction of the MSF Dataset(s) requested at the end of the Research;

2.2 Timing for requests for access

- 2.2.1 MSF will provide decisions to Requestors regarding applications within one (1) month after the MSF meeting deciding on the applications for access.

3. PROCESSING APPLICATIONS

3.1 Administrative checking

On receipt of the application, MSF will check to ensure that all required information has been supplied. If any information is missing from the application, the Requestor will be asked to supply this before the application is further considered.

3.2 Eligibility checking

- 3.2.1 MSF Data Sharing Committee will check whether each application complies with eligibility requirements set in article.

- 3.2.2 The decision regarding each application is final.

4. CONDITIONS OF ACCESS

Once transfer of requested MSF Dataset(s) has been accepted, and before transfer is effectively granted, Requestors must agree to the conditions of access set out below and return a signed MTA to MSF.

4.1 Signature of the MTA

- 4.1.1 No Transfer of MSF Dataset(s) shall be carried out by MSF without the signature of an MTA.
- 4.1.2 The MTA will be prepared by MSF and shall include the conditions described hereinafter.

4.2 Ethics approvals

- 4.2.1 In case the requested MSF Dataset contains Personal Data or Human Samples, or is subject to limits relative to the consent of Data Subjects described in article 1.2.3, the Requestor shall seek and obtain ethics approvals from HCECs and MSF ERB. In such case, MSF shall not transfer the requested MSF Dataset before written evidence of such approvals has been provided to MSF. The Requestor will be responsible to apply directly to the MSF ERB enclosing a copy of the preliminary approval letter from the DSC. The ERB will respond to the PI with a copy of their decision to the chair of the DSC.
- 4.2.2 The Recipient shall be responsible for seeking and obtaining all Host Country(ies) and international ethical, regulatory and legal approvals applicable that are necessary to carry out its Research, including with respect to the use of the requested MSF Dataset(s).

4.3 Compliance with laws and standards

- 4.3.1 The Recipient shall comply with all the laws, governmental rules, regulations and guidelines which are applicable to the use of MSF Datasets, including without limitation, Host Country(ies) and international best standards and rules relating to medical confidentiality, medical ethics and medical research.

4.4 Usage Limitation

- 4.4.1 MSF Dataset(s) transferred shall be used by Recipient solely for carrying out the Research stipulated in the application and described in the MTA;
- 4.4.2 MSF Dataset(s) provided shall only be used to the extent that is reasonably necessary to achieve the Research;
- 4.4.3 The Recipient shall not use MSF Dataset(s) for work on human subjects, including diagnostic testing, unless as expressly provided in its application, nor for commercial or for profit purposes.

4.5 Intellectual Property

4.5.1 The Recipient agrees that it shall not seek Intellectual Property rights of any kind, or any other protection in respect of Results, without MSF prior written consent.

4.6 No onward Transfer

4.6.1 MSF Datasets may not be transferred to any Third Party(ies) and can only be accessed by individuals directly involved in the Research and affiliated to the institutions responsible for the Research that have been declared in the application.

4.6.2 Recipients shall not use or store MSF Datasets at any facility outside of its control.

4.7 Protection of medical confidentiality and privacy

4.7.1 Recipients must agree not to link the MSF Dataset provided with any other dataset unless such link has been clearly declared in its application;

4.7.2 The Recipient shall not attempt to identify or contact any specific individual or groups of individuals or medical institutions whose data or Human Biological Material is included in MSF Datasets.

4.8 Publication(s) and Transparency

4.8.1 Recipients are expected to submit their results to a peer reviewed Publication in a manner consistent with MSF scientific publishing policy, which promotes open access publishing; to that extent, the Recipient shall use its best efforts not to enter into any copyright agreement that unreasonably restricts access in any way to electronic versions of any Publications, notably in light of potential public health benefits of releasing results immediately and without restrictions. It is understood that proper acknowledgement of the original researchers will be made.

4.8.2 Any Publication or presentation using MSF Dataset(s) shall include an acknowledgement using the text below:

“This Research includes data provided by Médecins Sans Frontières <and/ or Epicentre>. Médecins sans Frontières <and/ or Epicentre> <is/ are> not otherwise research partners or party to this Research”

4.8.3 Any other reference to MSF names, logos, or any adaptation of its trademarks requires prior authorisation of MSF.

4.8.4 Recipients should provide MSF with a copy of any Results or Publication based on MSF Dataset(s).

4.8.5 MSF may publish, at its own discretion, Research titles on its website, together with lay summaries, the names of the institutions and electronic contact details of the principal investigator of transferred Research.

5. DATA HANDLING FEES

- 5.1 The Recipient will be required to cover the costs of retrieving, processing and dispatching MSF Datasets. Details of these costs are available at <http://fieldresearch.msf.org/msf/> and further information can be obtained from data.sharing@msf.org
- 5.2 In case the Recipient does not have sufficient financial means to cover such fees, case-by-case exceptions can be made, at MSF sole discretion. In such case, the Requestor shall submit a specific written demand for fees' exemption with its application.

6. WITHDRAWAL OF CONSENT

- 6.1 Recipients of MSF Datasets that include Personal Data and/or Human Samples will be informed if a Data Subject withdraws its consent and will be required to delete the appropriate data rows and inform MSF in writing that this has been done.
- 6.2 The data handling fee is non-refundable if consent is withdrawn.

7. GOVERNANCE PROCESSES

- 7.1. A MSF Data Sharing Committee ('MSF DSC') will be in charge of processing and finalising all applications for MSF Dataset(s) included in the Collection. To that extent, the role of DSC is limited to determining if individual Requestors meet the eligibility criteria set out in the Data Sharing Policy and procedures.
- 7.2. MSF DSC composition shall vary from one data set to another, according to which MSF Dataset is requested and examined.
- 7.3. The composition of the MSF DSC will be decided by consensus amongst the Medical Director(s) of the Operational Directorate(s) that are Custodian of the requested MSF Dataset.
- 7.4. Composition of the MSF DSC shall normally be composed of 3 members drawn from the Operational Directorate(s) that are Custodian of the requested MSF Dataset. One member of each DSC should be considered a non-specialist in the topic area of the requested MSF Dataset. Members may be drawn from the following groups:
 - Representative of Operations and/or one representative of the Medical Department of each MSF sections that are the Custodian(s) of the MSF Dataset(s) requested and examined in the particular session;
 - Representative of Epicentre in case Epicentre is Custodian for MSF Dataset(s) requested and examined in the particular session;
 - Other members deemed relevant to the examination of the request by virtue of their areas of expertise

- 7.5. Each DSC will consider the application on the basis of the principles outlined in the present Data Sharing Policy. Permission will not be unreasonably withheld. In case the MSF DSC believes that the identity of a Requestor or that any element of an application may be used, intentionally or not, against the interests of MSF, it shall refer the matter for decision to the Medical Directors of the MSF entity(ies) that are Custodian of the MSF Dataset concerned.
- 7.6. Voting rights and modalities
- (i) The DSC will take decisions based on consensus. Failure to arrive at consensus will require referral to the MSF Medical Directors of MSF entities that are Custodian for the particular MSF Dataset(s) requested.
 - (ii) The decision of the DSC shall be final.

A representative of MSF legal department will be available on request of the DSC to advise members regarding Personal Data, Sensitive Data, the MTA and the overall legal framework of Transfers.

III PROCEDURES FOR INCLUSION OF MSF DATASET IN THE COLLECTION

8. *PROCEDURE FOR THE INCLUSION OF ROUTINELY COLLECTED DATA OR HUMAN SAMPLES*

8.1. Proposals for inclusion in the Collection of routinely collected data or Human Samples can be made by any MSF-Epicentre researcher or MSF Medical Working Group or MSF Medical Director. Where the proposal comes from an individual, it must be co-signed by at least 2 other MSF-Epicentre employees. The proposal should specify the following elements:

- Briefly describe how the data could contribute to the vision outlined in the policy document
- Precise the data involved including date, location of collection
- State if any limitations as described in section 1.2 apply to the proposed data

8.2. Decisions on the proposal will be communicated by the Medical Director(s) or his/her representative within 90 days of the date of the proposal.

9. *Procedure for the inclusion of data or Human Samples collected for Research*

9.1. A plan for data management and data sharing, including Human Samples, shall be included in relevant Research proposals, consistent with the policy

document and the procedures laid out for managed access in section II. Provision for first publication rights in the data sharing plan will be consistent with the Fort Lauderdale data sharing principles² where applicable.

- 9.2. Approval of the data sharing plan in the research proposal rests with the Medical Director(s) of the Operational Directorate(s) that are Custodian of the proposed data or Human Samples.

² <http://www.sanger.ac.uk/datasharing/assets/fortlauderdalereport.pdf>