

## HARTWIG MEDICAL FOUNDATION - RULES OF PROCEDURE DATA ACCESS REQUESTS

These 'Rules of Procedure Data Access Requests' were most recently updated as per 1 April 2020. Hartwig Medical Foundation may amend this publication policy at any time by publishing an amended version on its website.

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### 1 Definitions

1.1 In these Rules, the following terms which are listed in alphabetical order and which shall be identifiable by the use of (initial) capital letters, shall have the following meanings:

<b>Agreement</b>	the license agreement referred to in Clause 8 which sets out the terms, conditions and restrictions for access to and use of Licensed Data by an Applicant, and which shall be entered into between that Applicant and Hartwig Medical Foundation before such access to Licensed Data is granted;
<b>Annex</b>	an annex to these Rules;
<b>Applicable Legislation</b>	all relevant laws, regulations, guidelines, codes of conduct and other legislation as applicable from time to time, in particular legislation in relation to scientific research and the processing and protection of personal data, including but not limited to the General Data Protection Regulation (EU/2016/67) and the Dutch GDPR Implementation Act ( <i>Uitvoeringswet algemene verordening gegevensbescherming</i> );
<b>Applicant</b>	the individual, entity or organisation referred to in Clause 3.1 who submitted or on whose behalf was submitted a Data Access Request to Hartwig Medical Foundation;
<b>Articles</b>	the articles ( <i>statuten</i> ) of Hartwig Medical Foundation as applicable from time to time;
<b>Board</b>	the board ( <i>het bestuur</i> ) of Hartwig Medical Foundation;
<b>Board Decision</b>	a decision of the Board as referred to in Clause 7.1 regarding a Data Access Request;
<b>Business Day</b>	any day on which the banks are usually open for business in the Netherlands, excluding Saturdays, Sundays and public holidays;

<b>Clause</b>	any clause or sub-clause of these Rules;
<b>DAB Advice</b>	the advice from the Data Access Board to the Board regarding a Data Access Request as referred to in Clause 6.4;
<b>Data Access Board</b>	the data access board of Hartwig Medical Foundation established pursuant to clause 13 of the Articles, and operating in accordance with clause 13 of the Articles and these Rules;
<b>Data Access Request</b>	a request for access to and use of Foundation Data for research purposes, submitted by an Applicant to Hartwig Medical Foundation via a Data Access Request Form;
<b>Database</b>	a database containing pseudonymised/encoded medical, clinical and (DNA and/or RNA) sequencing data of (former) cancer patients, which database belongs to and is managed by Hartwig Medical Foundation;
<b>Data Access Request Form</b>	the standard form to be used by an Applicant for submitting a Data Access Request, including all appendices thereto and, where applicable, all accompanying documents and information provided by the Applicant;
<b>Evaluation Form</b>	the standard evaluation form used by the Board, the Scientific Council and the Data Access Board in their assessment of a Data Access Request;
<b>Foundation Data</b>	any and all encoded (medical, clinical and (DNA and/or RNA) sequencing) data included in the Database;
<b>Guiding Principles</b>	Hartwig Medical Foundation's guiding principles as applicable from time to time, which set out how the Foundation Data, the Database and Data Access Requests shall be handled by Hartwig Medical Foundation. The prevailing version of the Guiding Principles is available on the website of Hartwig Medical Foundation.
<b>Hartwig Medical Foundation</b>	the Stichting Hartwig Medical Foundation, a foundation ( <i>stichting</i> ) established under Dutch law with registered office at Science Park 408, (1098 XH) Amsterdam, the Netherlands, registered in the commercial register ( <i>handelsregister</i> ) held by the Dutch Chamber of Commerce under number 63052725;

<b>Licensed Data</b>	(the part of) the Requested Data that will be made available to an Applicant pursuant to a Board Decision as referred to in Clause 7.1 in accordance with the terms of an Agreement;
<b>Publication Policy</b>	Hartwig Medical Foundation's publication policy as applicable from time to time. The prevailing version of this Publication Policy is available on Hartwig Medical Foundation's website;
<b>Requested Data</b>	the Foundation Data to which a Data Access Request relates as determined by Hartwig Medical Foundation on the basis of the Data Access Request Form;
<b>Rules</b>	these 'rules of procedure data access requests' as applicable from time to time which set out how Hartwig Medical Foundation (i.e. the Scientific Council, the Data Access Board and the Board) shall handle Data Access Requests;
<b>SC Advice</b>	the advice from the Scientific Council to the Data Access Board as referred to in Clause 5.5 regarding a Data Access Request as laid down in the Evaluation Form;
<b>Scientific Council</b>	the Scientific Council ( <i>wetenschappelijke raad</i> ) of Hartwig Medical Foundation established pursuant to clause 14 of the Articles, and operating in accordance with clause 14 of the Articles and these Rules;
<b>Submission Date</b>	the date as referred to in Clause 4.1 on which a Data Access Request Form has been received by Hartwig Medical Foundation;
<b>Supervisory Board</b>	the supervisory board ( <i>raad van toezicht</i> ) of Hartwig Medical Foundation.

## **2 Scope of application**

2.1 These Rules apply to all Data Access Requests.

## **3 Submission of a Data Access Request and information requirements**

3.1 Any individual, entity or organisation (an **Applicant**) is entitled to submit a Data Access Request to Hartwig Medical Foundation.

3.2 A Data Access Request shall be submitted via a completed Data Access Request Form.

- 3.3 By submitting a Data Access Request Form, the respective Applicant and/or the researcher who submits the Data Access Request Form on its behalf:
- (i) warrants and represents that the information contained in the Data Access Request Form is complete, accurate and not misleading in any way;
  - (ii) warrants and represents that the information contained in the Data Access Request Form provides a sound view of all the aspects of the Data Access Request on which information is provided in the Data Access Request Form, it being understood that the information contained in the Data Access Request Form should enable Hartwig Medical Foundation to duly assess all relevant aspects of the Data Access Request in accordance with the Articles and these Rules;
  - (iii) warrants and represents that it/he/she is duly authorized to submit the Data Access Request (on behalf of the Applicant);
  - (iv) agrees that the Data Access Request shall be assessed by Hartwig Medical Foundation in accordance with the Articles, these Rules and the Guiding Principles;
  - (v) confirm(s) to have taken full account of the Guiding Principles and agrees to comply with these Guiding Principles; and
  - (vi) confirm(s) to have taken full account of the terms and conditions as included in the Agreement and confirms to enter into and comply with such (non-negotiable) Agreement in case its Data Access Request is (partially) granted.
- 3.4 Hartwig Medical Foundation is at all times entitled to request additional information from an Applicant relating to that Applicant's Data Access Request and/or Data Access Request Form and the Applicant shall comply with such information request(s).
- 3.5 Hartwig Medical Foundation is at all times entitled to request an Applicant to (re)submit a new and/or amended Data Access Request Form taking into account Hartwig Medical Foundation's instructions and the Applicant shall comply with such request.

#### **4 Admissibility of a Data Access Request**

- 4.1 Upon receipt of a Data Access Request Form by Hartwig Medical Foundation (the **Submission Date**), Hartwig Medical Foundation shall determine whether the Data Access Request is admissible. A Data Access Request shall in any event be inadmissible if:
- (i) the respective Data Access Request Form is incomplete;
  - (ii) the information contained in the respective Data Access Request Form is obviously inaccurate; or
  - (iii) Hartwig Medical Foundation in its sole discretion concludes, taking into account the Data Access Request Form, these Rules and the Guiding Principles, that there is insufficient basis for granting access to the Requested Data to the respective Applicant.

4.2 Hartwig Medical Foundation shall inform an Applicant on the (in)admissibility of its Data Access Request without undue delay.

4.3 In case of an inadmissible Data Access Request, the respective Applicant shall be allowed to (re)submit a new and/or amended Data Access Request Form.

4.4 In case of an admissible Data Access Request, Hartwig Medical Foundation will provide the Data Access Request Form and an Evaluation Form to the Scientific Council.

## **5 Scientific Council Assessment**

5.1 On the basis of the Data Access Request Form and the Evaluation Form, the Scientific Council shall assess the scientific aspects of the Data Access Request, in particular:

- (i) compliance with the Guiding Principles (insofar as these Guiding Principles relate to the scientific aspects of Data Access Requests);
- (ii) the scientific value and relevance of the (contemplated) research as specified in the Data Access Request Form;
- (iii) the relevance of the Requested Data for the (contemplated) research as specified in the Data Access Request Form;
- (iv) the feasibility of the (contemplated) scientific research as specified in the Data Access Request Form;
- (v) the (research) capacity and capabilities of the Applicant to execute the (contemplated) scientific research as specified in the Data Access Request Form; and
- (vi) other scientific aspects of the Data Access Request that the Scientific Council may deem relevant in its sole discretion.

5.2 The Scientific Council is entitled to adopt additional and/or more detailed criteria for its scientific assessment of Data Access Requests in consultation with the Supervisory Board at any time, which additional criteria shall be laid down in writing and may be added to these Rules as an Annex.

5.3 The Scientific Council may, in its sole discretion, consult external experts for advice on the scientific aspects of a Data Access Request and the Applicant agrees that its Data Access Request Form may be shared with such external experts on a confidential basis solely for this purpose.

5.4 The Scientific Council shall in any event consult an external expert, in case (i) Hartwig Medical Foundation obtained the Requested Data (partially or entirely) from a third party and (ii) Hartwig Medical Foundation is obliged to consult an external expert pursuant to a contract with such third party.

- 5.5 On the basis of its scientific assessment of a Data Access Request as set forth in this Clause 5, the Scientific Council shall advise the Data Access Board if, and if so, which (part of the) Requested Data can be made available to the Applicant (the **SC Advice**).
- 5.6 The SC Advice shall be substantiated and laid down in writing in the Evaluation Form. If the SC Advice concludes that (a part of) the Requested Data can be made available to the Applicant, the Scientific Council shall provide the Evaluation Form to the Data Access Board.
- 5.7 In case an SC Advice is not in accordance with the advice of an external expert as referred to in Clause 5.4, the advice of this external expert and the reasons for derogation from this advice shall be specifically addressed in the SC Advice.
- 5.8 If the SC Advice concludes that none of the Requested Data can be made available to the Applicant, the Scientific Council shall, notwithstanding Clause 5.5, provide the SC Advice directly to the Board and Clause 6 shall not apply. The Board may, however, in view of its entitlement under Clause 7.2, decide to ask the Data Access Board for its opinion.

## **6 Data Access Board Assessment**

- 6.1 On the basis of the Data Access Request Form and the SC Advice (in the Evaluation Form), the Data Access Board shall assess all (non-scientific) aspects of the Data Access Request, in particular:
- (i) compliance with the Guiding Principles (in particular insofar as these Guiding Principles relate to the non-scientific aspects of Data Access requests);
  - (ii) compliance with the Applicable Legislation (in particular in view of the Data Access Requests for commercial purposes, by commercial parties and/or by international parties);
  - (iii) compliance with any relevant contractual obligations, it being understood that this includes contractual obligations of Hartwig Medical Foundation but also relevant contractual obligations of third parties, in particular the third parties that provided (all or part of) the respective Requested Data to Hartwig Medical Foundation; and
  - (iv) societal and ethical aspects of the Data Access Request, including the (potential) impact on society and the impact from an ethical perspective of providing the Requested Data, it being understood that the credibility and reputation of Hartwig Medical Foundation and its Database is of the utmost importance to Hartwig Medical Foundation and its activities.
- 6.2 The Data Access Board is entitled to adopt additional and/or more detailed criteria for its assessment of Data Access Requests in consultation with the Supervisory Board at any time, which additional criteria shall be laid down in writing and may be added to these Rules as an Annex.
- 6.3 The Data Access Board may, in its sole discretion, consult external experts for advice on (the non-scientific aspects of) a Data Access Request and the Applicant agrees that its Data Access Request Form may be shared with such external experts on a confidential basis solely for this purpose.

6.4 On the basis of its assessment of (the non-scientific aspects of) a Data Access Request as set forth in this Clause 6 the Data Access Board shall advise the Board if, and if so, which (part of the) Requested Data can be made available to the respective Applicant (the **DAB Advice**).

6.5 The DAB Advice shall be substantiated and shall be laid down in writing in the Evaluation Form. The Data Access Board shall provide the Evaluation Form together with the respective Data Access Request Form, to the Board.

## **7 Board Decision**

7.1 On the basis of the Data Access Request Form, the SC Advice and, where relevant in view of Clause 5.8 the DAB Advice, the Board shall decide if, and if so, which (part of the) Requested Data (the **Licensed Data**) can be made available to the Applicant (the **Board Decision**) subject to Clause 8.

7.2 A Board Decision can only deviate from the SC Advice and/or the DAB Advice with the prior approval of the Supervisory Board.

7.3 The Board Decision shall be notified to the relevant Applicant without undue delay.

## **8 The Agreement**

8.1 Receiving access to Licensed Data by an Applicant is subject to that Applicant entering into an Agreement with Hartwig Medical Foundation setting out the terms, conditions and restrictions for access to and use of the Licensed Data. These terms, conditions and restrictions, which are not negotiable, are contained in the template Agreement that is available on the website of Hartwig Medical Foundation.

8.2 In case of Data Access Requests for commercial purposes or from a commercial party and this Data Access Request was approved in accordance with these Rules (whereby the Applicable Legislation was taken into account particularly), Hartwig Medical Foundation is allowed to request a fee, which fee shall be determined by Hartwig Medical Foundation taking into account, among others, (i) the amount of Licensed Data made available to the Applicant and (ii) the purposes as included in the Data Access Request Form for which these Licensed Data were requested. This fee shall be included in the Agreement between Hartwig Medical Foundation and the respective Applicant.

8.3 It shall be up to Hartwig Medical Foundation's sole discretion to determine, on the basis of the Data Access Request Form, whether it will request a fee. In this respect particular account shall be taken of whether the purpose for which the Foundation Data are requested by the Applicant will help to achieve Hartwig Medical Foundation's goals as set forth in the Articles and the Guiding Principles as applicable on the date on which the Agreement is entered into.

8.4 The Applicant may publish the results of its research pursuant to and in accordance with (article 8 of) the Agreement and in accordance with the Publication Policy as applicable at the date on which the Agreement is entered into.

## **9 Decision making principles**

- 9.1 The Data Access Board, the Scientific Council and the Board shall take due account of the Guiding Principles when handling a Data Access Request in accordance with these Rules.
- 9.2 The Scientific Council and the Data Access Board shall strive to reach consensus among its members with regard to all their decisions and advices taken or rendered pursuant to these Rules.
- 9.3 In case it is not possible to reach consensus with regard to a decision or advice as referred to in these Rules, the members of the Scientific Council or, as the case may be, the Data Access Board, shall vote on the decision to be taken or the advice to be given. In that case, each member of the Scientific Council or, as the case may be, the Data Access Board, shall have one vote and the decision to be taken or the advice to be given shall be determined by a simple majority. In case there is no simple majority for a decision or advice, the chairman of the Scientific Council or, as the case may be, the Data Access Board shall determine which decision is taken or which advice is given, taking into account the views of the other members.
- 9.4 The chairman of the Data Access Board or, as the case may be, the Scientific Council, shall have complete discretion with regard to the application of this Clause 9 and any decision taken pursuant thereto.

## **10 Miscellaneous**

- 10.1 All communications and notifications between Hartwig Medical Foundation and an Applicant in relation to a Data Access Request shall be made by email via the following email addresses:

Hartwig Medical Foundation

(including all its statutory bodies): [info@hartwigmedicalfoundation.nl](mailto:info@hartwigmedicalfoundation.nl)

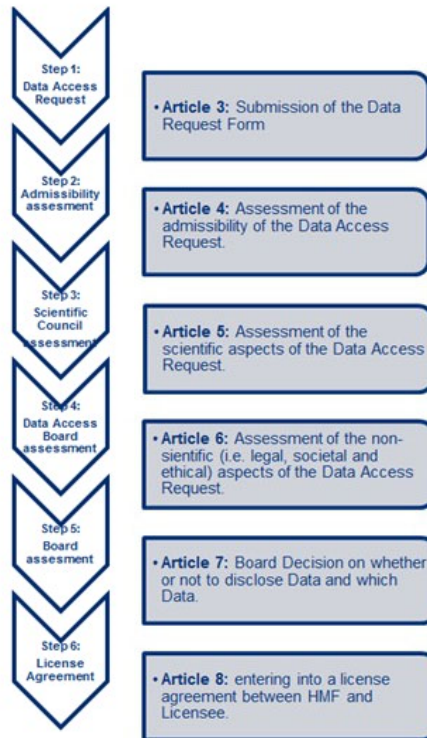
The Applicant: the email address in the Applicant's Data Access Request Form.

- 10.2 The members of the Scientific Council, the Data Access Board, the Board and all external experts which may be consulted pursuant to (Clauses 5.3,5.4 and 6.3 of) these Rules are subject to a duty of confidentiality both during and after their term of office and/or performance of their tasks pursuant to these Rules, with regard to any information which has come to their knowledge in the course of the performance of their tasks pursuant to these Rules.
- 10.3 The Evaluation Form, the SC Advice, the DAB Advice and any other documentation produced by or on behalf of Hartwig Medical Foundation pursuant to these Rules is exclusively produced for internal Hartwig Medical Foundation purposes and shall therefore never be provided to an Applicant or third parties.
- 10.4 Hartwig Medical Foundation strives to handle all Data Access Requests and taking the Board Decision as referred to in Clause 7, as swiftly as possible and ultimately within ninety (90)



Business Days after the Submission Date. This term/time period is indicative only, in particular, as the handling of Data Access Requests may be suspended for a period of time if the Applicant is requested to provide additional information (by the Board, the Scientific Council or the Data Access Board) or to submit a new and/or amended Data Access Request Form in accordance with Hartwig Medical Foundation's instructions, which is to be determined by Hartwig Medical Foundation in its sole discretion.

- 10.5 Hartwig Medical Foundation is entitled to amend and/or update these Rules at any time at its sole discretion by publishing an updated version on its website. Data Access Requests shall be handled in accordance with the Rules as applicable on the relevant Submission Date.
- 10.6 Any decisions or advices taken or rendered pursuant to these Rules, are not subject to appeal or any kind of (civil) remedy.
- 10.7 Pursuant to the Guiding Principles, Hartwig Medical Foundation is entitled to charge a fee for handling a Data Access Request if the assessment of such Data Access Request involves disproportionate time and efforts for Hartwig Medical Foundation compared to the (potential) benefits of the research project for which Foundation Data are requested. Hartwig Medical Foundation will only charge such fee after the Applicant has agreed to the fee suggested by Hartwig Medical Foundation in writing. In case the Applicant is not willing to pay the fee requested by Hartwig Medical Foundation, the respective Data Access Request will be deemed to have been withdrawn.
- 10.8 Applicants cannot derive any rights from these Rules.
- 10.9 The flow chart below is a schematic overview of the procedure regarding the handling of Data Access Requests as further detailed in these Rules:



These Rules were adopted by the Supervisory Board pursuant to and in accordance with clause 13.7 and clause 14.6 of the Articles.