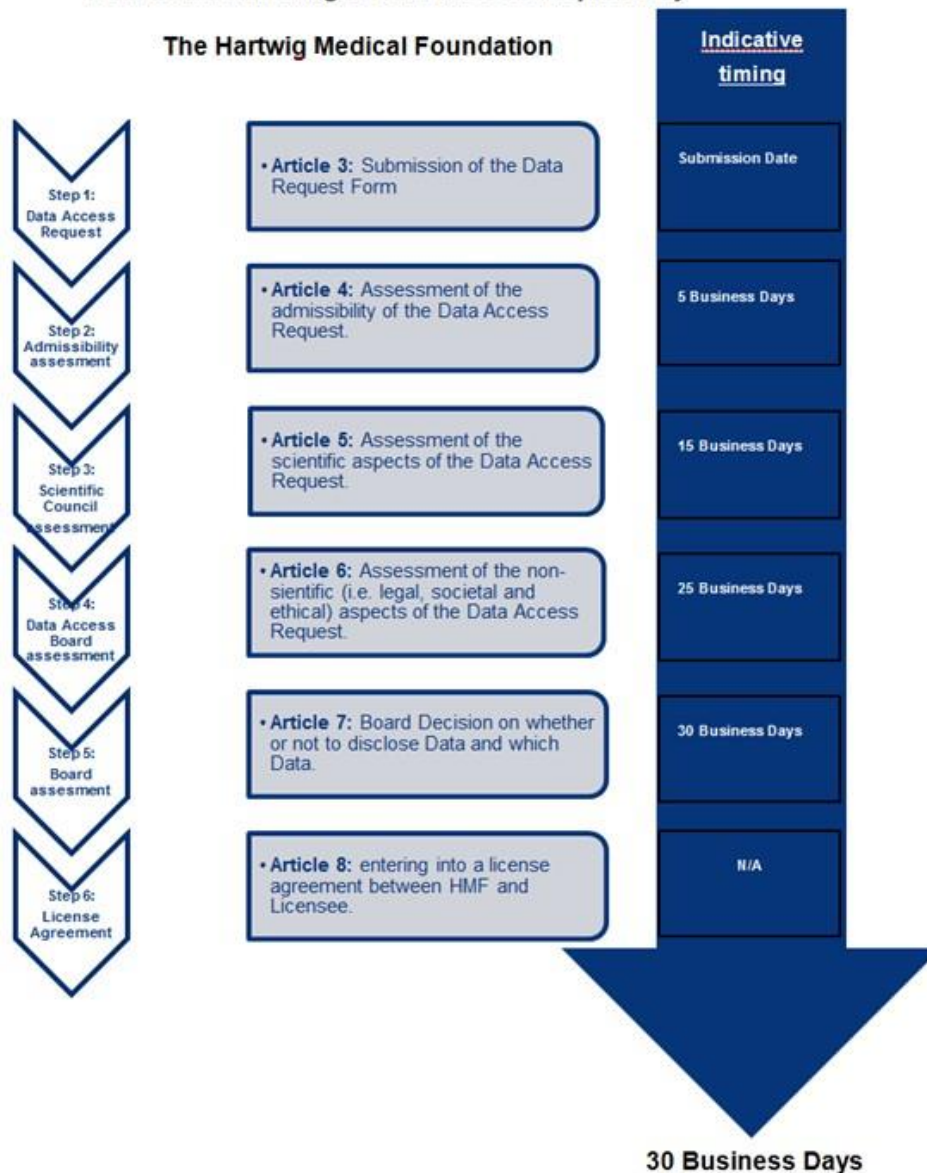


Hartwig Medical Foundation – Rules of Procedure Data Access Requests 2017

These 'Rules of Procedure Data Access Requests 2017' apply as of 1 January 2017 until 31 December 2018. The Hartwig Medical Foundation can amend these 'Rules of Procedure Data Access Requests 2017' at any time by publishing an amended version on its website. In the last quarter of 2017, these 'Rules of Procedure Data Access Requests 2017' shall be evaluated, after which the 'Rules of Procedure Data Access Requests 2018' will be published on the Hartwig Medical Foundation's website.

Flow Chart: Handling of Data Access Requests by



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:

Agreement	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 the Hartwig Medical Foundation before such access to Licensed Data is granted;
Annex	an annex to these Rules;
Applicable Legislation	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 protection of personal data, including but not limited to the Dutch Data Protection Act and, as of 25 May 2018, the General Data Protection Regulation (EU/2016/67);
Applicant	the individual, entity or organisation referred to in Clause 3.1 who or that submitted a Data Access Request to the Hartwig Medical Foundation;
Articles	the articles (<i>statuten</i>) of the Hartwig Medical Foundation as applicable from time to time;
Board	the board (<i>het bestuur</i>) of the Hartwig Medical Foundation;
Board Decision	a decision of the Board as referred to in Clause 7.1 regarding a Data Access Request;
Business Day	any day on which the banks are usually open for business in the Netherlands, excluding Saturdays, Sundays and public holidays;
Clause	any clause or sub-clause of these Rules;
DAB Advice	the advice from the Data Access Board to the Board as referred to in Clause 6.4 regarding a Data Access Request;

Data Access Board	the data access board of the Hartwig Medical Foundation established pursuant to clause 13 of the Articles, and operating in accordance with clause 13 of the Articles and these Rules;
Data Access Request	a request for access to and use of Foundation Data for research purposes, submitted by an Applicant to the Hartwig Medical Foundation via a Data Request Form;
Database	a database containing pseudonymised/coded medical, clinical and (DNA and/or RNA) sequencing data of (former) cancer patients, which database belongs to and is managed by the Hartwig Medical Foundation;
Data Request Form	the standard application form to be used by an Applicant for submitting a Data Access Request ;
Foundation Data	any and all (medical, clinical and (DNA and/or RNA) sequencing) data included in the Database;
Guiding Principles	Hartwig Medical Foundation's guiding principles as applicable from time to time, which set out how Foundation Data, the Database and Data Access Requests shall be handled by the Hartwig Medical Foundation. The prevailing version of the Guiding Principles are available at the website .
Hartwig Medical Foundation	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;
Licensed Data	(the part of) the Requested Data as referred to in Clause 7.1 that can be provided to an Applicant pursuant to a Board Decision as referred to in Clause 7.1 in accordance with the terms of an Agreement;
Publication Policy	Hartwig Medical Foundation's publication policy as applicable from time to time. The prevailing version of this Publication Policy is available at the website ;

Requested Data	the Foundation Data to which a Data Access Request relates as determined by the Hartwig Medical Foundation on the basis of the Data Request Form (cf. Clause 4.4);
Requested Data Overview	an overview of the Requested Data as referred to in Clause 4.4;
Rules	these ‘rules of procedure data access requests’ as applicable from time to time which set out how the Hartwig Medical Foundation (i.e. the Scientific Council, the Data Access Board and the Board) shall handle Data Access Requests;
SC Advice	the advice from the Scientific Council to the Data Access Board as referred to in Clause 5.5 regarding a Data Access Request;
Scientific Council	the scientific council (<i>Wetenschappelijke Raad</i>) of the Hartwig Medical Foundation established pursuant to clause 14 of the Articles, and operating in accordance with clause 14 of the Articles and these Rules;
Submission Date	the date as referred to in Clause 4.1 on which a Data Request Form has been received by the Hartwig Medical Foundation;
Supervisory Board	the supervisory board (<i>Raad van Toezicht</i>) of the 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 (the **Applicant**), is entitled to submit a Data Access Request to the Hartwig Medical Foundation.

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

3.3 By submitting a Data Request Form, the respective Applicant and/or the researcher who submits the Data Request Form on its behalf:

- (i) warrants and represents that the information contained in the Data Request Form is complete, accurate and not misleading in any way;
 - (ii) warrants and represents that the information contained in the Data Request Form provides a sound view of all the aspects of the Data Access Request on which information is provided in the Data Request Form, it being understood that the information contained in the Data Request Form should enable the 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 the 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 (unamended) Agreement in case its Data Access Request is (partially) granted.
- 3.4 The 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 Request Form and the Applicant shall comply with such information request(s) as soon as possible. The (indicative) terms and time periods provided by these Rules shall be suspended until the Applicant has replied to an information request of Hartwig Medical Foundation pursuant to this Clause 3.4 in a satisfactory manner, which is to be determined by the Hartwig Medical Foundation in its sole discretion.
- 3.5 The Hartwig Medical Foundation is at all times entitled to request an Applicant to (re)submit a new and/or amended Data Request Form taking into account the Hartwig Medical Foundation's instructions and the Applicant shall comply with such request as soon as possible. The (indicative) terms and time periods provided by these Rules shall be suspended until the Applicant has submitted the new and/or amended Data Request Form in accordance with the Hartwig Medical Foundation's instructions, which is to be determined by the Hartwig Medical Foundation in its sole discretion.
- 4 Admissibility of a Data Access Request**
- 4.1 Upon receipt of a Data Request Form by the Hartwig Medical Foundation (the **Submission Date**), the 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 Request Form is incomplete;
 - (ii) the information contained in the respective Data Request Form is obviously inaccurate; or
 - (iii) the Hartwig Medical Foundation in its sole discretion concludes, taking into account the Data 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 The Hartwig Medical Foundation shall inform an Applicant on the (in)admissibility of its Data Access Request within five (5) Business Days as of the Submission Date.
- 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 Request Form.
- 4.4 In case of an admissible Data Access Request, the Hartwig Medical Foundation shall determine to which specific Foundation Data the Data Access Request relates (the **Requested Data**) on the basis of the information contained in the respective Data Request Form. An overview of the Requested Data (the **Requested Data Overview**) shall be provided to the Scientific Council, together with the respective Data Request Form.

5 Scientific Council Assessment

- 5.1 On the basis of the Data Request Form and the Requested Data Overview, 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 Request Form;
 - (iii) the relevance of the Requested Data for the (contemplated) research as specified in the Data Request Form;
 - (iv) the feasibility of the (contemplated) scientific research as specified in the Data Request Form;
 - (v) the (research) capacity and capabilities of the Applicant to execute the (contemplated) scientific research as specified in the Data 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 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) the Hartwig Medical Foundation obtained the Requested Data (partially or entirely) from a third party and (ii) the 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 provided to the Applicant (the **SC Advice**). 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. The SC Advice shall be substantiated and shall be provided in writing to the Data Access Board, together with the respective Data Request Form and Requested Data Overview, in principle within fifteen (15) Business Days as of the Submission Date.
- 5.6 If the SC Advice concludes that none of the Requested Data can be provided 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.

6 Data Access Board Assessment

- 6.1 On the basis of the Data Request Form, the Requested Data Overview and the SC Advice, 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;
 - (iii) compliance with any relevant contractual obligations, it being understood that this includes contractual obligations of the 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 the Hartwig Medical Foundation; 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 the Hartwig Medical Foundation and its Database is of the utmost importance to the 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 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 provided to the respective Applicant (the **DAB Advice**). The DAB Advice shall be substantiated and shall be provided in writing, together with the respective Data Request Form, Requested Data Overview and SC Advice, to the Board, in principle within twenty-five (25) Business Days as of the Submission Date.

7 Board Decision

- 7.1 On the basis of the Data Request Form, the Requested Data Overview, the SC Advice and, where relevant in view of Clause 5.6, the DAB Advice, the Board shall decide if, and if so, which (part of the) Requested Data (the **Licensed Data**) can be provided 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 within thirty (30) Business Days as of the Submission Date except as otherwise indicated.

8 The Agreement

- 8.1 Receiving access to Licensed Data is subject to the Applicant entering into an Agreement with the 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. The (final) Data Request Form, as may have been amended and/or (re)submitted pursuant to Clause 3.5 or Clause 4.3, is published on the [website](#).
- 8.2 In case of Data Access Requests for commercial purposes or from a commercial party, the Hartwig Medical Foundation is allowed to request a fee, which fee shall be determined by the Hartwig Medical Foundation taking into account, among others, (i) the amount of Licensed

Data to which access is granted and (ii) the purposes as included in the Data Request Form for which these Licensed Data were requested. This fee shall be included in the Agreement between the Hartwig Medical Foundation and the respective Applicant.

8.3 It shall be up to the Hartwig Medical Foundation's sole discretion to determine, on the basis of the Data 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 will help to achieve the Hartwig Medical Foundation's goals as set forth 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 9 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 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 the Hartwig Medical Foundation and an Applicant in relation to a Data Access Request shall be made by email via the following email addresses:

The Hartwig Medical Foundation
(including all its statutory bodies): info@hartwigmedicalfoundation.nl

The Applicant: the email address in the Applicant's Data 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 (Clause 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 Requested Data Overview, the SC Advice, the DAB Advice and any other documentation produced by or on behalf of the 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 Terms and/or time periods provided by these Rules are indicative only and can therefore be extended by the Hartwig Medical Foundation at its sole discretion. The Hartwig Medical Foundation shall inform an Applicant on an extension of any term or time period provided by the Rules, including on the amount of Business Days by which the term or time period is extended, as soon as possible.
- 10.5 The Hartwig Medical Foundation is entitled to amend and/or update these Rules at any time at its sole discretion. 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 paragraph 3.23 of the Guiding Principles, the 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 the Hartwig Medical Foundation compared to the (potential) benefits of the research project for which Foundation Data are requested. The Hartwig Medical Foundation will only charge such fee after the Applicant has agreed to the fee suggested by the Hartwig Medical Foundation in writing. In case the Applicant is not willing to pay the fee requested by the 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.

These Rules were adopted by the Supervisory Board pursuant to and in accordance with clause 13.7 and clause 14.6 of the Articles on 30 november 2016.