

HARTWIG MEDICAL FOUNDATION – RULES OF PROCEDURE DATA ACCESS REQUESTS

These Rules were most recently updated as per 1 September 2026. Hartwig may amend these Rules from time to time.

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 agreement between Institution and Hartwig for the access of Hartwig Data from the Hartwig Medical Database, of which these Rules forms an integral part.
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 processing and protection of personal data, including but not limited to the General Data Protection Regulation (EU/2016/67) (Algemene verordening gegevensbescherming) (the GDPR) and the Dutch GDPR Implementation Act (Uitvoeringswet algemene verordening gegevensbescherming) (the UAVG) and including where applicable guidance issued by relevant authorities.
Applicant:	the individual requesting Hartwig Data from the Hartwig Medical Database.
Board:	the board of directors of Hartwig.
Board Decision:	a decision of the Board as referred to in Clause 7.1 regarding a Data Access Request.
DAB Advice:	the advice from the Data Access Board to the Board regarding a Data Access Request as referred to in Article 6.4.
Data Access Board:	the independent body that advises the Board on the legal, ethical and societal aspects of a Data Access Request.
Data Access Request:	the request for access to Hartwig Data, describing the purpose of the request and the use of the Hartwig Data.

Data Access Request Form:	the form provided by Hartwig for a Data Access Request, which has been filled in completely and signed by Applicant and Institution.
Evaluation Form:	the digital evaluation form used by the Board, the Scientific Council and the Data Access Board in their assessment of a Data Access Request.
Hartwig:	Stichting Hartwig Medical Foundation, a foundation dedicated to improving care for patients with cancer by, among other things, making data available for research.
Guiding Principles:	Hartwig's guiding principles, as amended from time to time, which form an integral part of the Agreement.
Hartwig Data:	any data included in the Hartwig Medical Database, which may include personal data.
Hartwig Medical Database:	the collection of clinical and genetic data of cancer patients (including any updates, additions and modifications thereto) compiled, facilitated and maintained by Hartwig, and which is systematically and methodically arranged and individually accessible by electronic means, and in respect of which a substantial investment has been made by Hartwig in obtaining, verifying and/or presenting its contents.
Institution:	the party (or in case of a multi-center request: parties) with which the Applicant is affiliated and on whose authorized signatory, together with the Applicant, signs the Data Access Request Form and who is a contractual party to the Agreement.
Publication Policy:	Hartwig's publication policy, as amended from time to time, which forms an integral part of the Agreement.
Researcher(s):	any individual(s) involved in conducting the research project described in the Data Access Request Form and authorized to access and use the Hartwig Data, including the Applicant where the Applicant itself is involved in the research project.
Rules:	these Rules of Procedure Data Access Requests, as amended from time to time and which form an integral part of the Agreement.
Scientific Council:	the independent body that advises the Board on the scientific aspects of a Data Access Request.

SC Advice: the advice from the Scientific Council to the Data Access Board as referred to in Article 5.5.

Supervisory Board: the supervisory board of Hartwig.

2. Scope of application

2.1 These Rules set out how Hartwig shall handle and assess Data Access Requests and apply to all Data Access Requests.

3. Submission of a Data Access Request and information requirements

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

3.2 Hartwig is at all times entitled to request additional information relating to a Data Access Request.

3.3 Hartwig is at all times entitled to request to (re)submit a new and/or amended Data Access Request Form taking into account Hartwig's instructions.

4. Admissibility of a Data Access Request

4.1 Upon receipt of a Data Access Request Form by Hartwig, Hartwig 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 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 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, the Data Access Request Form will be signed by Institution and Hartwig 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 Board at any time, which additional criteria shall be laid down in writing and may be added to these Rules.

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 On the basis of its scientific assessment of a Data Access Request as set forth in this Article 5, the Scientific Council shall advise the Data Access Board if, and if so, which (part of the) Hartwig Data can be made available. In case the Scientific Council has any questions, doubts or requires further clarification regarding a Data Access Request, the Applicant shall be given the opportunity to provide additional information or clarification. In case a Data Access Request is rejected, the respective Applicant shall be informed of the reasons for such rejection.

5.5 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 Hartwig Data can be made available, the Scientific Council shall provide the Evaluation Form to the Data Access Board.

5.6 If the SC Advice concludes that none of the Hartwig Data can be made available, the Scientific Council shall, notwithstanding Clause 5.5, provide the SC Advice directly to the Board and Article 6 shall not apply. The Board may, however, in view of its entitlement under Article 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 by international parties);
- (iii) compliance with any relevant contractual obligations, it being understood that this includes contractual obligations of Hartwig but also relevant contractual obligations of third parties, in particular the third parties that provided (all or part of) the respective Hartwig Data to Hartwig; 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 Hartwig Data, it being understood that the credibility and reputation of Hartwig and the Hartwig Medical Database is of the utmost importance to Hartwig 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 Board at any time, which additional criteria shall be laid down in writing and may be added to these Rules.

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.

6.4 On the basis of its assessment of (the non-scientific aspects of) a Data Access Request as set forth in this Article 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.

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 Article 6 the DAB Advice, the Board shall decide if, and if so, which (part of the) Hartwig Data can be made available (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 Applicant and Institution without undue delay.

8. Agreement and Fee

- 8.1 The license and access to Hartwig Data is subject to the conclusion of the Agreement with Hartwig which becomes effective upon the Board Decision containing written approval of a Data Access Request.
- 8.2 Hartwig reserves the right, at its sole discretion, to require the payment of a reasonable fee for costs and efforts by Hartwig in making the Hartwig Data available to Applicant and Researcher(s). Hartwig shall inform Institution as soon as possible in writing of any applicable fee setting out the details of the fee, and access to the Hartwig Data may be made conditional upon payment of such fee.
- 8.3 In determining whether Hartwig requires a reasonable fee, particular account shall be taken of whether the purpose for which the Hartwig Data are requested will help to achieve Hartwig's goals as set forth in the Guiding Principles and Hartwig's articles of association and whether the assessment of a Data Access Request involves disproportionate time and efforts for Hartwig compared to the (potential) benefits of the research project for which Hartwig Data are requested. In case the Applicant is not willing to pay the fee requested by Hartwig, the Institution may terminate the Agreement or the Data Access Request procedure with immediate effect.

9. Decision making principles

- 9.1 The Data Access Board, the Scientific Council and the Board shall take due account of the Guiding Principles and Hartwig's articles of association 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 Scientific Council or, as the case may be, the Data Access Board, shall have complete discretion with regard to the application of this Article 9 and any decision taken pursuant thereto.

10. Miscellaneous

- 10.1 All communications and notifications to Hartwig in relation to a Data Access Request shall be made by email via the following email addresses: dataaccess@hartwigmedicalfoundation.nl
- 10.2 The members of the Scientific Council, the Data Access Board, the Board and all external experts which may be consulted pursuant to 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 pursuant to these Rules is exclusively produced for internal Hartwig purposes and shall therefore never be provided to an Applicant or third parties.

10.4 Hartwig strives to handle all Data Access Requests and taking the Board Decision as referred to in Clause 7, as swiftly as reasonably possible and, when reasonably possible, 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's instructions, which is to be determined by Hartwig in its sole discretion.

10.5 Hartwig 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 signing date of the Data Access Request.

10.6 Any decisions or advice taken or rendered pursuant to these Rules, are not subject to appeal or any kind of (civil) remedy.

10.7 Institution, Applicant and/or Researcher(s) cannot derive any rights from these Rules.