

## HARTWIG MEDICAL FOUNDATION - GUIDING PRINCIPLES 2018

These 'Guiding Principles 2018' apply as of 25 May 2018 until 31 December 2018. Hartwig Medical Foundation may amend these Guiding Principles 2018 at any time by publishing an amended version on its website. In the last quarter of 2018, Hartwig Medical Foundation shall evaluate these Guiding Principles 2018, after which the 'Guiding Principles 2019' will be published on the Hartwig Medical Foundation website by 1 January 2019 at the latest.

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### 1 MISSION

1.1 **Hartwig Medical Foundation** has a clear mission: to promote advances in cancer research and the treatment thereof, with the aim of improving the healthcare for future cancer patients. Specifically, Hartwig Medical Foundation strives to ensure that every cancer patient receives the correct (and most effective) treatment, including the correct medication, at the correct time, in the correct period and at the correct dosage. There is still a great deal of progress to be made in this field, for instance through better use of the information that is already available.

*How does Hartwig Medical Foundation aim to achieve this?*

1.2 Hartwig Medical Foundation aims to achieve its mission by collecting and collating genetic and clinical data (including treatment data) from cancer patients in a single database. Data are always stored in encoded form (only with a patient code but without a name) so that the data cannot directly be related to an individual. Hartwig Medical Foundation is provided with this encoded genetic and clinical data by several hospitals, treatment centers and research institutes with whom Hartwig Medical Foundation has entered into specific arrangements.

1.3 Hartwig Medical Foundation has available *state of the art sequencing equipment*, which is used to sequence biological (human) material from cancer patients to generate genetic data. This process is always carried out on behalf of hospitals, treatment centers and research institutes with whom Hartwig Medical Foundation cooperates and also in an encoded form. Hartwig Medical Foundation may in these situations enter into agreements with these hospitals, treatment centers and research institutes to enable Hartwig Medical Foundation to store the generated (encoded) genetic data in its database.

1.4 The extensive, centralized information in the database offers many options and opportunities in the cancer research field. That is why Hartwig Medical Foundation makes data from the database available — under strict conditions — to certain parties, such as researchers and scientists. They can use the information from the database to conduct further research into cancer treatment and to learn more about such matters as how the disease develops and what the effects of various treatments are. In this document, the term 'treatment' should be read as including medication.

## **2 CORE VALUES**

2.1 Hartwig Medical Foundation applies the following core values:

- Contributing to (a more efficient form of) scientific research, in order to promote the development of new treatment methods and thus to contribute to the development of safe, effective and affordable treatment;
- Integrity. In other words: to handle data, including patients' personal data, in a reliable, careful, safe and transparent manner;
- To be a reliable partner for patients, research institutions, hospitals, academic institutions and experts, in order to promote scientific and social advances.

## **3 SAFEGUARDING THE CORE VALUES**

3.1 The aforementioned core values are essential for Hartwig Medical Foundation. They are non-negotiable and underlie all of Hartwig Medical Foundation's decisions. Hartwig Medical Foundation translates the core values into specific arrangements and goals as far as possible, and safeguards them from a variety of perspectives, namely (i) social, (ii) ethical, (iii) legal, and (iv) contractual.

(i) Social sphere

3.2 Society needs new, more efficient methods of cancer (treatment) research and development. The collection and exchange of data plays a central role here. A great deal is already possible in terms of technology — including the use of electronic patient records and eHealth applications — and a tremendous amount of information is available. Applying the available technology to the available information — in the right way — can lead to a huge step forward in the field of healthcare innovation.

3.3 For quite some time, there has been a trend within the healthcare sector towards sharing more information, improving the quality of available information and fostering increased — and better — collaboration. Parties such as Health-RI play an important role in this respect. For example, Health-RI has observed that many research results fail to reach patients that data become lost or cannot be used and that money is wasted as a consequence. It has also identified fragmentation of data, of organizations, and of the way in which resources and samples are handled. Health-RI's goal is thus to develop an efficient, high-quality research infrastructure, with sufficient attention being paid to procedure and regulations, alongside high-quality local facilities.

3.4 Hartwig Medical Foundation supports this goal and is contributing to this development. It does so by collecting genetic and clinical data (including treatment data) from cancer patients in a single database, and making those data available — under strict conditions — for scientific research.

- 3.5 An important difference with existing initiatives is that Hartwig Medical Foundation only stores and provides information / results from research on biological (human) materials, rather than the biological (human) materials itself (as well). This makes Hartwig Medical Foundation's activities essentially different from those of biobanks. Hartwig Medical Foundation is the first party in the Netherlands to facilitate advances in research into (the correct treatment of) cancer in this way. **Hartwig Medical Foundation is aware that it is thus venturing into (partly) unknown territory, and therefore regularly monitors the results and permissibility of its activities. Hartwig Medical Foundation engages (legal) assistance where necessary or desirable.**

*Nature of the data*

- 3.6 Naturally, Hartwig Medical Foundation is aware that it has sensitive, personal and confidential data at its disposal. It is precisely in a society where technology is widely available and information is shared to an increasing extent that both the patient and the practitioner must be able to rely on this taking place securely. **In Hartwig Medical Foundation's view, it goes without saying that data are to be collected and stored as securely as possible, taking account of the state of the art and the latest insights in the field of data security.** Hartwig Medical Foundation only has available encoded data. As a result, Hartwig Medical Foundation is not able to (directly) relate or link the genetic and clinical data to a specific patient. Naturally, Hartwig Medical Foundation also only stores data if and to the extent that this is possible pursuant to the applicable legislation and regulations. In addition, Hartwig Medical foundation ensures that no superfluous data are stored in the database. Hartwig Medical Foundation outsources its data processing and storage to a reputable IT company whose extensive expertise includes the data security field. Naturally, in this processes Hartwig Medical Foundation itself retains control of the database at all times.

*Data requests*

- 3.7 Hartwig Medical Foundation also handles (the assessment of requests for) access to data from the database with due care. Each request is tested and assessed by independent bodies of Hartwig Medical Foundation (the Scientific Council and the Data Access Board) using a clear, publicly accessible protocol (the Rules of Procedure Data Access Requests). Data are always retained and provided in coded form.
- 3.8 Hartwig Medical Foundation is aware that publishing scientific articles is an important way to advance research into cancer treatment. **However, with a view to careful data handling, not every research plan automatically qualifies for receipt of data from the database.** The plan must relate to innovative scientific and/or healthcare-economic research aimed at improving the collective healthcare system, improving/developing new treatment methods and/or improving/developing safe, effective and affordable cancer medication. The research must be relevant, new, feasible, and of social and/or scientific value. Moreover, the purpose of the research must align with Hartwig Medical Foundation's core values.

- 3.9 If data are provided by Hartwig Medical Foundation, these will be specific data (not the whole database) that, furthermore, may only be used for the relevant (specific) research purpose. Hartwig Medical Foundation's right to supervise and monitor use of the data is laid down contractually (in the agreements that Hartwig Medical Foundation concludes with the data recipients). For example, it is agreed that Hartwig Medical Foundation can ensure, at all times, that the recipient of the data actually uses the data (exclusively) for the contemplated research.
- 3.10 As Hartwig Medical Foundation is aware that supply chain responsibility is highly important, Hartwig Medical Foundation's contracting parties are also required to apply the above guiding principles (such as the purpose limitation requirement) themselves.
- 3.11 If Hartwig Medical Foundation itself wishes to make use of the data from its database (in the context of the external provision of data), the same rules and protocols apply to Hartwig Medical Foundation as to external parties. One of the implications of this is that Hartwig Medical Foundation, too, must submit its request to the Scientific Council and Data Access Board for assessment.

#### *Publications*

- 3.12 The publication of research results based on the data made available by Hartwig Medical Foundation is important for scientific advances and, as such, is supported by Hartwig Medical Foundation. **Hartwig Medical Foundation takes an independent position as regards the conducting of research, and does not concern itself with the content of any publication of research results.** In addition, Hartwig Medical Foundation will not, for example, claim intellectual property rights in third party discoveries resulting from data provided to those third parties. Hartwig Medical Foundation applies a certain publication policy (which can be found on <https://www.hartwigmedicalfoundation.nl/en/data-policy/>).

#### *Collaboration*

- 3.13 Hartwig Medical Foundation is aware **that social and scientific advances cannot be made without collaboration.** That is why Hartwig Medical Foundation seeks to collaborate with patients, hospitals, academic institutions, interest groups and experts where possible. The basic principle here is that each party does what it is good at; Hartwig Medical Foundation brings parties together and facilitates the appropriate and efficient use of medical and research data. Supply chain responsibility plays a central role here; each link in the chain must handle (the other parties') data and interests in an ethical manner.
- 3.14 Where possible, Hartwig Medical Foundation also wants to promote collaboration in scientific research; if the same question emerges from various centers or research institutes, the advice will be to join forces in a single research project.

#### (ii) Ethical sphere

- 3.15 There is a growing awareness in society of the value of personal data (including medical data). This means that there is a greater need for openness and participation regarding the use of personal data. Hartwig Medical Foundation is aware of this, and considers transparency about the use of data to be of paramount importance. Hartwig Medical Foundation handles data ethically; it is, for example, fully open about what it does with personal data and why. Hartwig Medical Foundation describes this in (inter alia) its [Privacy Policy \(which can be found on https://www.hartwigmedicalfoundation.nl/en/data-policy/\)](https://www.hartwigmedicalfoundation.nl/en/data-policy/).

*Informed consent*

- 3.16 **In principle, Hartwig Medical Foundation only works with 'informed consent' from patients and strives to offer patients options for controlling the use of their data.** Under the applicable legislation and regulations the genetic data and health data that are processed by Hartwig Medical Foundation qualify as 'special categories of personal data'. Hartwig Medical Foundation has designed its processing activities and policies in such way that these comply with the strict requirements that apply to this type of data.
- 3.17 However, in some case Hartwig Medical Foundation works with data from patients whose biological (human) material was taken quite some time ago (in case of retrospective studies). In those cases, it may be arguable that the informed consent pursuant to which the biological (human) material was obtained is inadequate to serve as a sufficient (legal) basis for Hartwig Medical Foundation's activities (which, after all, were not known about when the relevant biological (human) material was taken, as Hartwig Medical Foundation did not yet exist at that time).
- 3.18 In so far as possible, in such cases Hartwig Medical Foundation will proceed to attempt to obtain adequate informed consent or to arrange for it to be obtained (and naturally to comply with the other conditions for lawful processing). However, that is not always possible or practically feasible, for example where the patient in question has died in the interim. Under certain circumstances, the public interest that Hartwig Medical Foundation seeks to serve, justifies Hartwig Medical Foundation working with personal data in these situations as well (in so far as the patient did not object to that at the time). Obviously, an important condition in this respect is that the privacy and medical interests of any patients concerned are (otherwise) sufficiently safeguarded in accordance with these Guiding Principles. In these situations Hartwig Medical Foundation only acts after the interests involved have been carefully balanced.
- 3.19 In addition, Hartwig Medical Foundation is aware that processing of personal data could be hampered or obstructed in the event that patient data are not (sufficiently) anonymous, or if sufficient (or sufficiently clear) informed consent has not been obtained. In such cases, Hartwig Medical Foundation can imagine that a socially compelling research interest may justify overriding possible privacy objections. The nature and objectives of the research play an important role in this regard (research into a ground-breaking method of treatment at an advanced stage may more readily provide such justification than research with a less direct social benefit/interest). Obviously, this is subject to the condition that legal limits are respected and that the invasion of privacy is so minor that that patient can still trust that his or her data will

be handled with due care. Hartwig Medical Foundation is aware that continuous vigilance is required to safeguard the privacy of patients. The Data Protection Officer of Hartwig Medical Foundation assists in this respect. Where possible, Hartwig Medical Foundation also seeks to **collaborate with interest groups** in this respect. For example, Hartwig Medical Foundation believes that patients' associations have a role to play in sharing their thoughts about participation and control options for patients (particularly with regard to retrospective studies).

3.20 **When information is requested, a careful assessment is made as to whether the (intended) data use falls within the scope of the patient's informed consent. Hartwig Medical Foundation exercises restraint where the informed consent is insufficiently clear.** The patient and the practitioner are entitled to this, and must be able to trust that their data will be handled with due care.

3.21 **On the other hand, Hartwig Medical Foundation strives to avoid scientific research being unnecessarily obstructed by an overly strict interpretation of open standards and grey areas in the applicable legislation and regulations.** Without scientific research, the development of new, better or more efficient treatment methods would be impossible. To conduct such scientific research, patient data are necessary.

#### *Commercial use*

3.22 In accordance with the legal requirements for processing personal data, Hartwig Medical Foundation works in the public interest, without a profit motive. This means, for example, **that Hartwig Medical Foundation ensures that data from its database are only used in accordance with its objectives (scientific research in the public interest).** If commercial parties (such as pharmaceutical companies) can contribute to Hartwig Medical Foundation's mission (contributing to advances in cancer research and treatment), Hartwig Medical Foundation will wish to facilitate this. However, this would only be possible in the event that the research of commercial parties serves a public interest. Hartwig Medical Foundation will assess whether this requirement is met in each specific case. Naturally, requests from such parties for the provision of data must also pass the same test via the Data Access Board and the Scientific Council (i.e. the Rules of Procedure Data Access Requests). Hartwig Medical Foundation will never permit the use of data for marketing or similar purposes.

#### *Fees*

3.23 **If Hartwig Medical Foundation decides to provide data in a case as referred to in 3.22 above, Hartwig Medical Foundation could request a fee for this. In addition, Hartwig Medical Foundation may also request a fee if a request for data requires disproportionate effort on the part of Hartwig Medical Foundation.** These fees are directly fed back to the Foundation and are thus fully applied in furtherance of Hartwig Medical Foundation's objectives and mission: the advancement of scientific research into (the treatment of) cancer. Data will never be 'sold'; all that is provided is a (contractual) right to use specific data (from the database) for a specific research question.

*Patients' control options*

3.24 **The basic principle is that, at all times, the patient retains control of the data that he or she has provided.** Specifically, this means that a patient always has the option of inspecting his or her data, having it deleted or lodging an objection to the (further) use of the data. As Hartwig Medical Foundation itself has no direct contact with the patient (Hartwig Medical Foundation does not know from which patients it stores personal data), the institutions that provide Hartwig Medical Foundation with data have an essential role to play in offering and implementing the control options. In this respect, Hartwig Medical foundation makes arrangements with the institutions involved.

(iii) Legal sphere

3.25 Naturally, Hartwig Medical Foundation takes a great deal of care in setting up, using and providing access to the database. Thus, for example, Hartwig Medical Foundation knows and respects its legal limits and what it can and cannot do under, inter alia, the General Data Protection Regulation (“**GDPR**”) and the Dutch General Data Protection Regulation (Implementation) Act (“**UAVG**”) Medical Treatment Contracts Act (*Wet op de geneeskundige behandelingsovereenkomst*). Hartwig Medical Foundation has its methods legally assessed in collaboration with a designated team of attorneys.

3.26 In the event that Hartwig Medical Foundation encounters **grey areas in the legislation and regulations, it tests the limits of what is permissible** where that is necessary to advance cancer research and development. In doing so, Hartwig Medical Foundation applies **the following principles** in any event:

- patients' privacy is always respected. Personal data are processed in an honest, careful and transparent manner;
- the technical and organizational protection and security of data is essential;
- data are processed in coded form, such that Hartwig Medical Foundation will not be able to identify the patients whose data it is managing;
- the data used are adequate, up to date, relevant and not excessive;
- Hartwig Medical Foundation uses and/or provides data from the database exclusively for the purposes for which Hartwig Medical Foundation received the data. Therefore, data are always used to foster advances in cancer treatment and research. The data provided or stored never exceed what is necessary for those purposes;
- in principle, Hartwig Medical Foundation only processes data with adequate consent from the patient. Because Hartwig Medical Foundation has no direct contact with the patient, Hartwig Medical Foundation ensures that the parties providing the data, such as hospitals and treatment centers, have obtained the informed consent. The agreements concluded by Hartwig Medical Foundation contain various provisions in that respect. If — as regards

prospective studies — no (valid) consent has been obtained, Hartwig Medical Foundation cannot and will not proceed to store or provide patient data until the moment that sufficient informed consent that covers the processing has been obtained. Where retrospective studies are concerned, Hartwig Medical Foundation applies the principles described in paragraphs 3.16-3.21 above;

- Hartwig Medical Foundation ensures that data are processed within the European Union (EU) as far as possible. If it is necessary to take the data outside the EU, Hartwig Medical Foundation will guarantee a sufficient security level for the data. The receiving party must, at the very least, comply with all regulations that apply within the EU.

3.27 As well as complying with the applicable legislation and regulations, Hartwig Medical Foundation seeks **alignment with codes of conduct** drafted on a self-regulation basis (such as 'Human Tissue and Medical Research: Code of Conduct for Responsible Use' (*Code Verantwoord omgaan met lichaamsmateriaal ten behoeve van wetenschappelijk onderzoek*) drawn up by the Foundation Federation of Dutch Medical Scientific Societies). As long as it does not interfere with Hartwig Medical Foundation's mission, Hartwig Medical Foundation applies the 'best practice' principle when handling data (thus doing more rather than less where possible, even when less is permissible).

(iv) Contractual sphere

3.28 As long as it is in line with Hartwig Medical Foundation's mission and core values, Hartwig Medical Foundation applies the basic principle that data from the database should be accessible to everyone. **Partners must share (and conform to) Hartwig Medical Foundation's core values and must agree to the** (strict) conditions that Hartwig Medical Foundation imposes with regard to patient privacy and data protection.

3.29 Hartwig Medical Foundation also safeguards its core values contractually, by, for example, **making clear arrangements about such matters as data use** in its collaboration agreements and license agreements. In addition, the Rules of Procedure Data Access Requests are contractually incorporated into relevant agreements, thus assuring compliance with the safeguards included therein. Consent and transparency obligations are, where relevant, contractually imposed on parties that receive data, and these parties are furthermore subject to contractual restrictions on what they can do with the data. Use for marketing purposes is excluded, for example, and it is not possible to sell data or make data available to others. Arrangements of a more practical nature are also made, for example regarding the transfer of clinical data, the supply of samples and the manner in which data are provided (in coded form).

3.29.1 Hartwig Medical Foundation also puts **transparency** first and foremost vis-a-vis its partners, for example regarding expectations, progress, costs and conditions in respect of the collaboration. In addition, Hartwig Medical Foundation is prepared to make (model) agreements available to interested parties, if so requested with a view to transparency or for other reasons.

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