

Annex 6: General terms and conditions of NCR Data provision

General terms and conditions of NCR Data provision

version 1.2 September 2019

Article 1 – Applicability

- 1 These general terms and conditions of NCR Data provision (hereafter referred to as: “General Terms and Conditions”) apply to the Agreement and to all future data deliveries of NCR Data to the Applicant by iKNL.
- 2 Alterations and supplements to these General Terms and Conditions are only valid if agreed to in writing between the parties.

Article 2 – Definitions

Application Form the form that iKNL provides to Applicants for an NCR Data Application. This form must be completed and signed by the Applicant.

Applicant the party that applies to iKNL for provision of data from the NKR.

Data Linkage the linkage created when an Applicant applies for NCR Data with data from another source – whether or not originating from the Applicant.

NCR Data personal data originating from the NCR.

Data Subject the person to whom personal data relates.

NCR Data Application the Application Form submitted by the Applicant to iKNL requesting provision of NCR Data, in which the purpose of the Application is described.

NCR Data Provision at the request of the Applicant, the provision of NCR Data by iKNL.

NCR the Netherlands Cancer Registry, the national database of data on cancer among the Dutch population on a personal level, which is maintained by iKNL.

Agreement the Agreement between iKNL and the Applicant on the basis of which – not necessarily with Data Linkage – iKNL provides NCR Data and to which these General Terms and Conditions apply. The Agreement is concluded by both the Applicant and iKNL signing the Application Form in conformity with Article 3.2 of these General Terms and Conditions.

Article 3 - NCR Data Application

- 1 Applicant uses the Application Form to apply for the required NCR Data at iKNL. iKNL issues the Application Form to the Applicant per request. Request of the Application Form may be submitted via gegevensaanvraag@iknl.nl or via www.iknl.nl. The Applicant must complete all relevant sections and sign the Application Form and submit it to iKNL, upon which iKNL further processes the Application.
- 2 Following receipt of the Application Form, completeness of the Application Form and feasibility of the application is assessed by iKNL. Following assessment, iKNL completes the sections of the Application Form pertaining to iKNL and, where necessary, adds additional specific (financial) conditions. iKNL returns the Application Form, including these General Terms and Conditions, to the Applicant, thereby requesting the Applicant to approve the Application Form with a signature of a duly authorised representative. The Application Form signed by the Applicant should then be returned to iKNL. The Agreement is established when it has been received by iKNL.
- 3 The NCR Data Provision Assessment Framework (“Toetsingskader Gegevensaanvragen NKR”) applies to the provision of NCR Data. This document may be obtained via gegevensaanvraag@iknl.nl per request.
- 4 NCR Data may only be provided by iKNL to the Applicant if the conditions in the above-mentioned Assessment Framework have been met and/or the necessary internal procedures have been followed by iKNL.

Article 4 – Data Linkage

- 1 This article only applies if the Applicant's Application concerns Data Linkage.
- 2 The Applicant guarantees that
 - i. insofar as required, explicit consent of the Data Subject(s) has been obtained for, or at any rate is otherwise authorised to provide data to iKNL and/or conduct Data Linkage with the NCR;
 - ii. the data have been legally obtained; and
 - iii. the data will be transferred as specified according to the ‘Format database linkage’ as provided by iKNL to the Applicant. The above-mentioned also applies to the Applicant if the data is provided by a third party to iKNL at the request of the Applicant.
- 3 iKNL is entitled to renounce delivery of data if the linkage result is not deemed sufficiently reliable. iKNL reserves the right to request supplemental personal data and/or information from the Applicant if the linking file is considered insufficient for Data Linkage.
- 4 The result of the Data Linkage will be discussed in mutual consultation with the Applicant, and the requested NCR Data will be provided to the Applicant if the linkage results is deemed sufficiently reliable by all parties concerned to achieve the Applicant's objectives.
- 5 In the event that iKNL is required to supply NCR Data to a third party to establish linkage of NCR Data with data from another source, the Applicant is responsible for the actions by this third party in accordance with relevant laws and regulations, including the General Data Protection Regulation. In this context, the Applicant is at least obliged – as for the above-mentioned NCR Data – to impose the obligations in Articles 6 and 7 of these General Terms and Conditions (or equivalent obligations) on the third party to whom iKNL also delivers NCR Data at the request of the Applicant.
- 6 In case of a Data Linkage involving a third party, a separate agreement will be entered into with Applicant and this third party, unless iKNL decides otherwise. The General Terms and Conditions also apply to this agreement.

Article 5 – Right of Use of NCR Data

- 1 Any intellectual property rights, particularly database rights regarding the collection of NCR Data is vested in iKNL.
- 2 iKNL grants the Applicant a non-exclusive, non-transferable right of use of NCR Data for a duration of five (5) years. If the Applicant is legally required to retain NCR Data beyond five (5) years, or in case a longer period is necessary to meet the objectives of the NCR Data Application by the Applicant, the Applicant may request iKNL to grant the right of use for a longer period.
- 3 If the Applicant acts in breach of the Agreement concluded between iKNL and the Applicant and/or other arrangements made including these General Terms and Conditions, iKNL is entitled to (i) subject the right of use granted to the Applicant to further conditions and/or (ii) terminate the right of use granted. The Applicant is obliged to immediately terminate usage of the NCR Data and destroy the NCR Data upon notification to this effect by iKNL.
- 4 The right of use granted by iKNL only applies to those within the Applicant's organisation involved in activities in the context of the objectives stated in the Application Form. Provision of NCR Data by iKNL to a third party at the Applicant's request qualifies as provision of a subuser right to the Applicant's NCR Data to this third party. This subuser right is exclusive and non-transferable and is valid for the duration of the period for which this is required but will never exceed the duration of five (5) years, unless iKNL decides otherwise as stated in writing.
- 5 iKNL is entitled to use the NCR Data for its own objectives, unless explicitly otherwise agreed to in writing.

Article 6 - Prudent Use

- 1 Parties shall act in accordance with the General Data Protection Regulation (AVG) (EU/2016/679) and allied laws and regulations.
- 2 The Applicant has a legal basis, as referred to in Article 6 of the General Data Protection Regulation (GDPR), and an exception as

referred to in Article 9 (2) of the GDPR, to be able to make legitimate use of NCR Data or to legitimately process NCR Data.

- 3 The Applicant treats the NCR Data provided by iKNL with due care and acts in accordance with applicable laws and regulations and codes of conduct relating to protecting personal data and scientific research.
- 4 The Applicant verifies that the NCR Data provided by iKNL are usable and correct (for the objective(s) for which the NCR Data have been requested as stipulated in the Application Form) and, if this is not the case, testifies to immediately destroy the NCR Data and to immediately inform iKNL to this effect.
- 5 The Applicant uses the NCR Data solely for the objectives and research question(s) stated in the Application Form. The Applicant is obliged to submit a new NCR Data Application to iKNL for any other (re)use of NCR Data, including additional research, or when making NCR Data available to third parties.
- 6 If, at the Applicant's request, the NCR Data should also be sent by iKNL to a third party, the Applicant is responsible for this third party to act in accordance with relevant laws and regulations, including the General Data Protection Regulation (AVG). In this context, the Applicant is at least obliged – as for the above-mentioned NCR Data – to impose the obligations in Articles 6 and 7 of these General Terms and Conditions (or equivalent obligations) on the third party to whom iKNL also provided NCR Data at the request of the Applicant.

Article 7 - Privacy and Information Security

- 1 The Applicant is obliged to take appropriate technical and organisational measures to ensure and to demonstrate that the processing of NCR Data takes place in accordance with applicable laws and regulations. For that purpose, the Applicant is obliged to secure the NCR Data provided by iKNL against loss or against any form of unlawful processing, including unauthorised access by third parties.
- 2 The Applicant is not allowed to retain the NCR Data provided by iKNL in a form which renders Data Subject(s) potentially identifiable for longer than is necessary to achieve the objectives as defined in the Application Form. The Applicant is obliged to destroy the NCR Data provided by iKNL when the objectives have been achieved or when the right of use mentioned in Article 5 has lapsed. If, at the request of the Applicant, NCR Data is provided by iKNL to a third party, the Applicant is responsible for ensuring that this third party destroys the NCR Data when the subuser right lapses, the objectives have been achieved, and/or if iKNL requests Applicant to do so.
- 3 The Applicant shall – except in the case of Data Linkage – not endeavour to track down the identity of the Data Subject(s).
- 4 The Applicant and those persons deployed by it are not allowed to make unauthorised use of the NCR Data and will adhere to the security procedures and instructions maintained by the Applicant in accordance with paragraph 2 of this article.
- 5 The Applicant is not allowed to provide the NCR Data to third parties, except insofar as (i) the parties explicitly agree to this in writing, (ii) the Applicant is obliged to do so by or pursuant to the law, or (iii) the Applicant has obtained the explicit consent from iKNL for this purpose. If, on grounds of a statutory obligation, the Applicant is obliged to provide NCR Data to a third party, the Applicant is required to verify the motivations and the identity of the third party, and immediately inform iKNL of this information, and if possible, before provision of the data.
- 6 If, at the request of the Applicant, iKNL is to supply NCR Data to a third party, the Applicant will prohibit this third party from transferring the data to other third parties, unless iKNL consented to this in writing or in case the third party is obliged to do so by or pursuant to the law. The Applicant shall also impose the obligation on the third party, in the event that the latter is to transfer NCR Data to other third parties on grounds of a statutory obligation, to verify the legal basis as well as the identity of these other third parties, and to immediately inform both the Applicant and iKNL of this information, and if possible, before provision of the data.

Article 8 – Timeline(s)

- 1 The timeline(s) as stated in the Application Form or communicated otherwise by iKNL are indicative and entail a duty to make an effort to deliver the NCR data according to the agreed schedule.
- 2 iKNL is entitled to renounce delivery of NCR data if the data and/or ensuing results are not deemed sufficiently reliable. iKNL shall consult with the Applicant in case of renunciation.

Article 9 – Liability

- 1 iKNL endeavours to provide NCR Data that are accurately and up-to-date, but this is subject to accurate and up-to-date provision of data by third parties.
- 2 iKNL is not responsible and/or liable for provision of incorrect or incomplete NCR Data resulting from inaccurate and/or incomplete information provided by the Applicant in the Application Form.
- 3 iKNL is not responsible and/or liable for any loss suffered by the Applicant and/or third parties, arising directly or indirectly out of or in connection with the provision of NCR Data and is neither responsible for the quality of the interpretation methods used in the context of scientific research, if iKNL itself is not involved and has neither been able to exercise any influence in or on the relevant scientific research, unless such loss arises because of a shortcoming by iKNL in fulfilment of its obligations arising from the existing Agreements between the Applicant and iKNL including these General Terms and Conditions. The abovementioned limitation does not apply in case of intent or gross negligence on the part of iKNL.
- 4 The Applicant shall indemnify iKNL against claims from Data Subjects and/or third parties because of a breach or non-compliance by the Applicant of obligations toward iKNL arising pursuant to the Agreements made between the abovementioned parties including these General Terms and Conditions and/or from the legal provisions for protecting personal data.
- 5 The maximum total liability of iKNL for an attributable failure in the performance of the Agreement or any other reason, including any failure to observe a warranty obligation agreed with the Applicant, shall be limited to a reimbursement of the direct damage up to a maximum of the amount covered by insurance.
- 6 In the event that the insurer does not provide insurance, or in case of damage not covered by insurance, the maximum total liability of iKNL shall be limited to a reimbursement of the direct damage up to a maximum of the amount of the price stipulated in the Agreement (excl. VAT). In the event that the Agreement constitutes a continuing performance contract with a duration of more than 1 year, the aforementioned amount will be set to the total of the agreed price (excl. VAT) charged tot the Applicant in the twelve months preceding the occurrence of the damage.
- 7 Any liability on the part of iKNL for indirect loss, consequential loss, loss of earnings, loss of savings, reduced goodwill, loss due to suspension of business, or damage associated with software, equipment or services by third parties, is excluded.
- 8 The abovementioned limitations do not apply in case of wilful misconduct or gross negligence on the part of iKNL.

Article 10 – Publication and Acknowledgement of Source

- 1 If iKNL has contributed to interpretations of NCR Data, the Applicant shall include iKNL as a co-author in publications in accordance with the most recent version of the guidelines on authorship of the International Committee of Medical Journals Editors.
- 2 The Applicant shall mention iKNL in the acknowledgements of publications (example text: *"The authors thank the registry team of the Netherlands Comprehensive Cancer Organisation (iKNL) for the collection of data for the Netherlands Cancer Registry"*).
- 3 The Applicant shall provide iKNL a copy of any publication arising from the use of NCR Data, within four weeks following publication.
- 4 iKNL is entitled to impose additional terms and conditions with respect to publications.

Article 11 – Force Majeure

- 1 Force majeure is understood to mean any shortcoming in the fulfilment of obligations arising from the Agreement and/or arrangements made between iKNL and the Applicant, which cannot be attributed to one party, because it is not due to the fault of iKNL nor the Applicant, and neither being for the account of iKNL nor the Applicant pursuant to the law, judicial acts, or generally accepted practice.
- 2 If temporary force majeure occurs on the part of iKNL, pursuant to its obligations under the Agreement and/or other arrangements, iKNL may suspend its obligations during the force majeure.
- 3 If the force majeure on the part of iKNL lasts longer than three (3) months, iKNL may terminate its obligations pursuant to the Agreement and/or other arrangements, without iKNL being obliged to pay compensation for loss which the Applicant may have suffered or will suffer.

Article 12 – Terms of Payment

- 1 Any prices and rates charged by iKNL are in Euro and exclude turnover tax and other government levies, unless the parties have explicitly agreed to otherwise in writing.
- 2 iKNL is entitled – without prior written notification – to increase the agreed rate as at 1 January of each year by the maximum wage increase agreed to in the collective labour agreement for hospitals and changes in government levies for the year, irrespective of the commencement date of the wage adjustment in this year. The collective labour agreement for hospitals applicable for iKNL, in which the structural and incidental development of the wage adjustment are determined (salary scales, holiday allowance and end-of-year bonus), apply here as a starting point. If the collective labour agreement for hospitals is determined after 1 January, the 10-year average collective labour agreement wage development will be applied.
- 3 Payment of the invoice by the Applicant must be made within thirty (30) days after the invoice date to a bank account designated by iKNL, unless agreed to otherwise in writing. The term of payment as meant in this paragraph is a strict deadline. If the Applicant does not ensure payment of the invoice within the specified period, as from the due date the Applicant shall be in default without further notice of default and from that moment, iKNL may charge default interest of 1% per month on the outstanding amount, unless the statutory interest rate is higher, in which case the statutory interest is due. Interest on the immediately payable amount will be calculated from the moment the Applicant is in default until the moment of payment of the full amount due.
- 4 The Applicant may never offset the amounts due to iKNL.
- 5 The Applicant must immediately notify iKNL of any inaccuracies in payment details provided or specified.

Clause 13 – Termination

- 1 The parties may terminate the Agreement with immediate effect by submitting a written notice of termination if:
 - a. the other party has been granted provisional suspension of payments or has been put into liquidation or has applied for a debt restructuring scheme or is placed under guardianship or administration;
 - b. the other party ceases its business operations in whole or in part, or otherwise winds up, or substantially alters its business activities or transfers its business activities to a third party.
 - c. the competent authorities institute an investigation into the other party or impose a measure/penalty on this party in relation to applicable privacy laws and regulations.
- 2 If a party attributively fails in the fulfilment of any obligation vested in it pursuant to the Agreement and/or any other existing arrangements between the parties, the other party may terminate the Agreement only after the failing party has been granted a reasonable period to perform properly by the other party;
- 3 If termination of the Agreement is attributable to the Applicant or when this occurs at his risk, the Applicant must compensate the direct and indirect loss which iKNL consequently suffers.
- 4 If iKNL terminates the Agreement through cancellation or dissolution, iKNL may order the Applicant to destroy the NCR Data already delivered. The Applicant must provide conclusive evidence to iKNL of the abovementioned destruction at iKNL's first request.
- 5 iKNL is entitled terminate the Agreement with immediate effect without any notice of default in the event that continuation of the NCR Data Application (or Agreement) may no longer be reasonably demanded from iKNL for compelling legitimate grounds, without in that case there being an obligation to pay compensation or any other payment on the part of iKNL.
- 6 Provisions that are by their nature intended to continue after the dissolution of the Agreement shall remain in force between parties.

Clause 14 – Applicable Law and Disputes

- 1 Dutch law applies to the Agreement.
- 2 Any disputes arising from and/or in connection with the Agreement, on exclusion of other district courts, must be brought before the competent court in Utrecht. Parties agree to firstly consult with one another and attempt to resolve any conflict that may arise over (the interpretation or implementation of) this Agreement, including the option of appointing a mediator in mutual consultation.

Article 15 – Final Provisions

- 1 The Applicant is not permitted, without prior written consent of iKNL, to transfer its rights and/or obligations to third parties.
- 2 If one or several provisions in these General Terms and Conditions at any point in time are annulled or declared void entirely or in part, then

the remainder in these General Terms and Conditions remain applicable. iKNL and the Applicant must then consult with one another to agree on (a) new provision(s) to replace the void or voidable provision that takes account of the purpose and scope of the original provision(s). If consultations do not lead to a reasonably acceptable solution, the parties may terminate the Agreement and/or arrangements with due observance of a notice period of two (2) months.

version 1.2: September 2019

Valid

Version	Date
1.0	1-9-2018
1.1	19-2-2019
1.2	9-9-2019