Title:	**Data confidentiality**	
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Please note that storage and release of biological samples are removed from this policy and are now described in the HOVON Biobanking policy.

Trial data ownership

The HOVON foundation is the owner of the data collected according to the protocol of a clinical (intervention) or observational trial for which HOVON is the primary sponsor, unless this is otherwise specified in a contract or other legal document.

Details on data ownership or data use in any trial in which HOVON is involved, either as sponsor or partner/co-sponsor, may be specified in a trial agreement with the parties involved.

Patient data confidentiality (privacy) and informed consent in HOVON trials

All data and samples collected in a HOVON trial will be coded to protect patient confidentiality (privacy). No directly identifying data will be collected from patients. At enrolment only gender and year of birth[1)] will be recorded, for the purpose of statistical analysis and to verify eligibility. A patient study number will be assigned to each patient at enrolment.

Only the local investigator enrolling the patient in the trial and if necessary his/her study staff has access to the key to unlock the code and link the patient study number to a specific person.

No data may be collected from a patient's medical record without prior written informed consent. The patient's informed consent is limited to the collection of data from the patient's medical record that is relevant for the purpose of the trial as described in the protocol (objectives and endpoints). This includes secondary data necessary for the correct evaluation and analysis of the trial endpoints (e.g. medical history, off-protocol treatment).

The Principal Investigator of a HOVON sponsored trial should ensure that the protocol, CRF and other trial related documents (forms, manuals) are in accordance with this policy.

Confidentiality of data collected by HOVON in association with biological samples

For more information, please refer to the HOVON Policy Biobanking. The following is an excerpt from that policy.

Sample labels and accompanying documents should be coded using the HOVON trial number and the patient study number in the trial. The sample label should also include a description of the contents (bone marrow, EDTA blood, etc.) It is allowed to add the following data for administrative purposes: date and time of sample extraction, gender of the patient, year of birth of the patient, hospital where sample was collected.

In some trials samples may need to be collected and shipped after informed consent (possibly using a "pre-study ICF") but prior to enrolment in the trial and therefore prior to assignment of a patient study number. In those trials patients should be issued a screening-number by HOVON at the time that the samples are collected. The screening-number should be recorded on the sample label. If and when the patient is enrolled in the trial, the link between screening-number and patient study number should be recorded and shared with the biobank. If it is not possible to issue screening-numbers in a trial, it is allowed to record the full date of birth, to ensure that samples can be attributed to the correct patient after inclusion in the trial. At inclusion of a patient in such a trial, the date of extraction of samples that have been sent in prior to inclusion may be recorded in the enrolment database as an additional safe-guard for correct attribution of samples.

An exception to the coding and privacy requirements described above, is allowed for samples that are not collected solely for research purposes, but are also used to generate test results that are of significance for the treatment of the patient. The sample is tested at the central facility and the result is returned to the site, where it is used to make a decision regarding the patient's treatment. In this situation, any risk that the test result cannot be reliably attributed to the correct patient by the site, is unacceptable. In a trial where this is the case, study specific measures should be taken to mitigate this risk. The chosen procedure still has to comply with privacy laws, and should be described in the trial protocol.

Use of trial data for other research

The use of data collected in a HOVON trial for other scientific research is only allowed after approval of the HOVON executive board, who will consult the relevant working group.

HOVON will only allow the use of trial data (i.e. data present in a central database) for other research under the following circumstances:

- The investigator provides HOVON with a research proposal describing the purpose of the research and the data requested from HOVON.
- The investigator agrees to use the provided data for the purpose of the described research only, and will not share or forward the data to any other party or person without permission of HOVON.
- The project leaders of the research project should obtain regulatory approvals for their project if applicable.
- It concerns scientific research with an objective that is in line with the HOVON objective "To promote optimum treatment of adult patients with malignant hematological diseases", meaning the project aims to contribute to a better understanding of hematological disease or to the improvement of diagnostic procedures or treatment options.
- The research purpose must fall within the scope of the consent given by patients
- The investigator will publish the results in a scientific journal and/or at a congress, or will otherwise make the results available to the scientific community.
- Only data that are relevant to the research purpose are provided.
- Data for secondary analyses or meta-analyses and data for the analysis of additional scientific research with stored samples are provided to the investigator coded with patient study number. References to site name and year of birth are removed and replaced by a site number and age information (e.g. age at enrolment, age at diagnosis).
- Data collected from the Dutch Hematopoietic Stem Cell Transplantation Registry may only be used for other research if renewed permission from the hospital department who entered the data in the registry is obtained.

Specific guidelines for data requests from commercial organizations

If data are requested for use in research that is performed by a commercial organization, the request should be discussed by the HOVON executive board.

Specific attention is needed to verify that the conditions are met regarding the contribution to the HOVON objective, e.g. scientific and clinical relevance, and that the research purpose is in line with the consent that was given.

The HOVON executive board may decide to put additional conditions on the use of data by a commercial organization.

[1)] by the effective date of this policy, the enrolment database used by the HOVON Data Center requires to enter a full date of birth. Until the time when the HDC has migrated to a new enrolment database that allows entering a partial date (year of birth only), it is allowed to deviate from this part of the policy.