**[Survey/Retrospective/Non-Interventional Prospective] study protocol for the [name Working Party] as was approved by:**

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| **Principal Investigator** Date of approval *(dd/mm/yyyy)*: \_\_/\_\_/\_\_\_\_ |
| Name: |  |
| Signature: |  |
| **Working Party Chair** Date of approval *(dd/mm/yyyy)*: \_\_/\_\_/\_\_\_\_ |
| Name: |  |
| Signature: |  |
| **Working Party Study Coordinator** Date of approval *(dd/mm/yyyy)*: \_\_/\_\_/\_\_\_\_ |
| Name: |  |
| Signature: |  |
| **Working Party Statistician** Date of approval *(dd/mm/yyyy)*: \_\_/\_\_/\_\_\_\_ |
| Name: |  |
| Signature: |  |

Before initiation of the study, the Working Party (WP) Study Coordinator will ensure that the Principal Investigator (PI), potential co-investigators and any other involved party have signed the **EBMT non-disclosure agreement (NDA**).

1. Title of the study

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| Full title: |  |
| Short title: |  |

1. Working Party (WP)

**To be filled in by the WP Study Coordinator/Data Manager.**

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| Working Party: |  |
| Chair: |  |
| Study Coordinator: |  |
| Data Manager: |  |
| Statistician: |  |
| WP email address: |  |
| *If applicable:* |
| Subcommittee: |  |
| Subcommittee Chair: |  |
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| *If applicable*, collaboration with other WPs: |
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| *If applicable*, collaboration with other partners:*(e.g. SCETIDE, PIDTC, CIBMTR, EUROCORD, etc.)* |
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1. Principal investigator (PI)

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| --- | --- |
| Name: |  |
| Email address: |  |
| CIC: |  |
| Department: |  |
| Hospital: |  |
| City: |  |
| Country: |  |
| Conflict of interest: □ Yes □ NoIf yes, please list: |
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1. Protocol version history

*(At least indicate the date of the first accepted protocol version and, if applicable, each subsequent amendment. Keeping track of the draft versions is optional. Number versions as follows: First protocol draft: v0.1, first accepted protocol: v1.0, first amendment: v2.0, etc.)*

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| Version number | Date *(dd/mm/yyyy)* |
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1. Rationale & background

*(State why you think it is necessary to conduct this study (minimum 200 words), keeping in mind previous (WP) studies that have already been conducted into the topic; use the ‘10. References’ section to list references)*

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1. Main objective and research questions

*(Explain your study and define your main objective in approx. 150 words*

*Example of a main objective: “Investigate the predictors of long-term survival after treatment”)*

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1. **Primary research question**

*(Describe the primary question you intend to answer with this study*

*Example: “What is the role of donor type and age in predicting long-term survival after treatment?”)*

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1. **Secondary research questions**

*(Describe the secondary questions you intend to answer with this study*

*Example: “How do donor type and age predict long-term survival in elderly patients? What is the role of cytogenetics in predicting long-term survival after treatment?”)*

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1. Study design

*(****In collaboration with the WP Statistician****:*

*Include: Proposed study type (Survey/Retrospective/Non-Interventional Prospective, Registry-based/additional data collection)*

*Time-points during treatment and follow-up when data will be collected (e.g. at diagnosis, at treatment, at follow-up, etc.)*

*Estimation of study time horizon (e.g. from start of conditioning until three months after transplant, within one year after infection, etc.)*

*In case of a non-interventional prospective study, estimation of duration of inclusion)*

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1. Study population

*(Precisely describe the study population with diagnosis, type of treatment, age, period analysed, stem cell source, etc.)*

1. **Inclusion criteria**

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1. **Exclusion criteria**

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1. **Sample size**

*(****In collaboration with the WP Study Coordinator/Data Manager and Statistician****: If a feasibility check was performed, provide the number of eligible patients in the EBMT Registry. If possible, give an estimation of the number of centres/patients expected to be included (based on the number of eligible patients and the expected response rate). In case of a non-interventional prospective study, provide the power calculation if performed)*

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1. Data collection & statistical analysis

All data collection will be performed by the WP Study Coordinator/Data Manager according to EBMT guidelines.

1. **Study variables**

*(List all variables to be collected and at which timepoints (e.g. at diagnosis, at treatment, at 1-year follow-up). Indicate which variables are needed for descriptive purposes only, and which should be considered in outcome analysis. Also indicate which variables are considered ‘key variables’, essential to the study’s main objective and imperative to obtain for each centre/patient. Consult the EBMT data collection forms to check whether the required data is collected on the Core/Extended forms)*

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1. **Endpoint(s)**

*(****In collaboration with the WP Statistician****: Define the endpoint(s) for analysis with the time horizon and define the competing events for any competing risks analysis*

*Example of an endpoint: Relapse-free survival 1 year after transplant)*

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1. **Statistical methods**

*(****To be completed by the WP Statistician****: Give a clear description of the statistical methods of analysis)*

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1. References

*(Please use a maximum of 10 references)*

1. Data sharing

Please note that EBMT will **not** share data with PIs from non-member centres, either aggregated or at patient-level, unless approval was obtained from the Executive Committee of EBMT (ExCOM) and the Data Protection Officer (DPO).

Before conducting a study with EBMT, the PI, potential co-investigators and any other involved party are required to sign the **EBMT non-disclosure agreement (NDA**) arranged by the WP Study Coordinator.

(Please note that when sharing patient-level data, EBMT will take into account the minimisation principle of the GDPR (2016/679) Art. 5(c), which entails that only minimal items necessary for the purpose will be shared, while complete datasets and datasets containing identifiers or outcomes will never be shared. For studies on rare diseases (i.e. studies including less than 30 patients) complete datasets can be shared without identifiers. If any exception is required, the approval from the ExCOM and the DPO shall be requested.)

When a patient has consented to share their data with third parties, EBMT and the third party will sign a **Data Processing Agreement (DPA)** or **Data Sharing Agreement (DSA)** arranged by the DPO.

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| Will data be shared with a third party? □ Yes □ NoIf yes, please specify what third party will have access to the data, whether this access relates to aggregated or patient-level data, and specify the reason: |
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| If it relates to patient-level data, please specify the variables for which patient-level data sharing with a third party is required: |
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1. Authorship

**To be filled in by the WP Study Coordinator/Data Manager.** The EBMT Publication Guidelines apply to this study. Please note that the first author and senior author positions on the authorship list must be discussed and agreed upon beforehand, as well as any arrangement deviating from the standard (e.g. shared first authorship, joint studies, etc.).

1. **Writing committee**

*(List all people who will be actively involved in manuscript writing and review, and indicate who will be first and last author)*

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1. Please send this form to:

**To be filled in by the WP Study Coordinator/Data Manager.**

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| **Working Party Study Coordinator:** |
| Name: |  |
| Email address: |  |