

**EBMT Nurses Group Research Committee – Research Proposal Form**

**This form enables your proposal to be registered with the EBMT Nurses Group (NG). Registration will mean that your proposal will be reviewed by the Nurses Group Research Committee (RC). Review by the RC allows the Committee to identify where and in which ways a research proposal can potentially be supported by the EBMT NG. Registration and review in itself does not constitute adoption of the research.**

* The intention of this process is:
* To ensure the proposer(s) of research study ideas retains ownership.
* To encourage nurses to present ideas and aspirations for research within a wider European setting.
* To provide specialist support and advice regarding research planning, development and implementation.
* To identify areas of interest to EBMT members where collaborative research may be undertaken.
* To ensure a comprehensive portfolio of nursing based research within the field of stem cell transplantation.
* To ensure that research has the best possible chance of being developed effectively and supported appropriately by EBMT NG.

**Registration Process**

Please complete the form below and email to the Nurses Group Study Coordinator: EBMT\_NursesGroup@lumc.nl

Please contact them if you require help completing this form.

**Development Process**

1. The Nurses Group Study Coordinator (SC) will issue a registration id no. (YY/NNN) and add details of the proposal to the register of proposals.
2. The SC will forward the proposal to the RC Chair.
3. The Chair of the RC will forward the synopsis to the other NG RC members.
4. Two selected NG RC members will review the proposal in detail and will discuss the outcome with all NG RC members.
5. The NG RC chair (or representative) will send a summarized response to the proposer.
6. The SC will contact other relevant EBMT NG members (Statisticians office and Business development manager) for comments and input, if required.
7. Funding issues related to the study should be clearly addressed in the proposal.
8. The RC members may support the proposal, ask the proposer for clarifications and discuss the proposal further, or reject the proposal. The Chair or designee (SC or RC member in charge of the study) will provide feedback to the PI.
9. The proposer(s) along with at least two members of the RC will form a Protocol Development Group (PDG).
10. The RC will request an update from the PDG, at approximately quarterly intervals.
11. The RC NG will report to the main EBMT NG at each of the 6 monthly meetings.
12. The PDG will finalise the study proposal outline, which should be sent, before submission, to the RC and EBMT NG for a letter of support.
13. The RC will provide a summary report of the outcome of all registered ideas/proposals in the EBMT NG Annual report and relevant meetings.

|  |  |
| --- | --- |
|  | **Date of Request: .. / .. / ..****Date of approval Chair: .. / .. / ..***Please note that approval is necessary before the proposal/feasibility check can be submitted to the Study Unit!* |

***Study request proposal for the***

***EBMT Nurses Group (NG) Research Committee***

***EBMT NG Research Committee chair:***

**Annika M Kisch**

***Title of the study:***

*(Please do not use more than 15 words)*

***Principal investigator:***

*(Name, department, hospital, city, country)*

***Co-investigator(s):***

*(Name, department, hospital, city, country)*

***Abstract (max. 350 words)***

*(Summarize your study proposal in max. 350 words (excl. trial registration nr. and keywords) with following headings:*

Background and rational:

Aims:

Methods:

Discussion:

Trail registration (if applicable):

Key words (max. 10 words):

***Introduction and rational of this study:***

*(State background, gaps and rational for this study in approx. 200 words; add references)*

***Primary objective:***

*(Describe the primary aim you intend to achieve with this study)*

***Secondary objectives:***

***Methods (max. 300 words):***

*(Explain in max. 300 words the methods of your study)*

***Design***

***Setting and sample*** *(Expected number of patients, diagnosis, type of transplant, age, period analysed,* *sampling, stem cell source, inclusion criteria, exclusion criteria)*

***Variables and measurement*** *(explain at what time-points during treatment and follow-up data will be asked for, e.g., at diagnosis, at transplant, at 6 months after transplant, List all research variables to be collected, list all outcome variables to be analysed)*

***Data sources:***

***Duration of the study:***

* ***Expected start of the study:***
* ***Expected completion of the study:***
* ***Criteria to close patient inclusion:*** *(date inclusion will start, estimation of date inclusion will be closed, length of follow-up, can patients be included retrospectively and if so, define period)*

***Data analysis*** *(give a brief description of the method of analysis)*

**All data collection will be performed by the Leiden** **Study Unit according to EBMT guidelines.**

***Expected impact for research and clinical practice:***

***Ethical approval (if applicable):***

***Trail registration number (if applicable):***

***Study budget:***

*Please note that for any funding for research conducted through or in collaboration with EBMT (whether EBMT is seeking the funding directly or another group is seeking funding for a project involving EBMT) all documentation should be provided to the EBMT NG Research Committee and EBMT NG Board.*

***Purpose of your study request:***

*(Paper, Presentation, etc.)*

***Publication:***

***The EBMT Authorship guidelines apply to this proposal.***

 ***Writing Committee***

*(list all people involved)*

***Approval***

***Signature NG President***  ***Signature RC chair***

***Name:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Name:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_***

***Signature Study Unit manager Signature EBMT statistician***

***Name:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Name:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_***

***Time schedule*** *(to be completed by the Study Unit)****:***

***(Planning of preparative work (designing forms), data collections, first interim analysis, completion of study entry, final analysis, report)***

Timeline

|  |  |
| --- | --- |
| Preparative work |  |
| Inclusion participants  |  |
| Data collection |  |
| Data processing and analysis |  |
| Report preparation |  |
| Final manuscript and co-author list check by the Study Unit |  |
| Total time needed |  |

***Please send this form to:***

**Nurses Group Study Coordinator:**

Brian Piepenbroek

EBMT\_NursesGroup@lumc.nl

***You can also contact:***

**EBMT NG Research Committee chair:**

Annika M Kisch

annika.kisch@med.lu.se