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|  | **Study Administration Code**  **..........**  (to be completed by the study office) |

**FULL STUDY TITLE**

**(Short study title: acronym or 3-5 key words**

**Examples: EASIX, SFAST, T-replete haplo with PTCy, Pharmacokinetics of busulfan)**

A STUDY FROM THE **TRANSPLANT COMPLICATIONS WORKING PARTY (TCWP)**

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| --- | --- |
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**Document changes tracker & study status follow-up**

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| --- | --- | --- | --- |
| Version | Date | Name | Brief summary of modifications |
| v0.1 |  |  | First draft of proposal sent to TCWP chair |
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**Subcommittee**

☐ Early complications and regimen-related toxicities

☐ Graft-versus-host disease

☐ Survivorship

☐ Artificial Intelligence

1. **Background & Rationale**

* Specify the reasons for conducting the research in light of current knowledge
* Include a well-documented statement of the need/problem that is the basis of the project, the cause of this problem and its possible solutions
* Answer to the questions:
  + Why the research needs to be done?
  + What will be its relevance?
* Give a brief description of the most relevant studies published on the subject

1. **Study objectives**

* State the objectives of the study
* Explain what the proposal/protocol hopes to accomplish
* Objectives should be simple (not complex), specific (not vague), and stated in advance (not after the research is done)
* Only one primary objective
  1. **Primary objective**
  2. **Secondary objective(s)**

1. **Study design**
   1. **Type of study**

* Describe precisely the study design, how it is related to the study objectives

**☐** Retrospective

**☐** Prospective, non-interventional (NIS)

**☐** Survey

* 1. **Study population**
* Describe precisely the research population
* For NIS studies, indicate the number of patients needed (describe calculation if so)
  + 1. **Inclusion criteria**
    2. **Exclusion criteria**

1. **Data management**
   1. **Data requirements**

* Provide a list of all the variables needed for the study
* Put them in different categories (transplant variables, conditioning, transplant complications, …)
  1. **Data feasibility & Data collection [Study Coordinator]**
* Give the number of potential eligible patients in the registry (for retrospective studies)
* Is it necessary to collect more data? If yes, describe the procedure
* Provide an estimation of the data collection period (this will evolve during the protocol writing process)

1. **Statistical analysis** 
   1. **Endpoints**

* The endpoints refer directly to the objectives and are the specific expression of what will be compared in the study
* Only one primary endpoint
  + 1. **Primary endpoint**
    2. **Secondary endpoint(s)**
  1. **Statistical methods [Biostatistician]**
* Define the outcomes associated to each endpoint
* Give a brief description of methods of analysis used to answer each objective, statistical tests, …
* Define statistical significance, confidence intervals, statistical software, …

1. **Study budget (when applicable)**
2. **Publication**

* The study will follow Authorship Guidelines for EBMT Publications.
  1. **Publication rules**
* EBMT rules of publication will be used. The order of the authors will be discussed in function of the amount of work given on each manuscript and the number of cases included. All co-authors will receive the draft of the manuscript to allow them to give their input. All centres will be included either in the authors or if there are too many names in an appendix.
  1. **Writing committee**
* List the people who will participate in scientific writing (abstract, poster, publication) and/or review

1. **References**

* References of literature cited in preceding sections in format:

[1] …

[2] …