**Policy regarding** **Data sharing / Authorship / Sub-analysis**

**Study Title**

**ReLatIonship BEtween implementation of evidence-based and suppoRtive ICU cAre and ouTcomes of patIents with acute respiratOry distress syndrome ～LIBERATION Study～**

Principal Investigator

Teikyo University Hospital

Kensuke Nakamura

1. **Data sharing**

The use and analysis of collected data will be performed with definite permissions by participating sites at the time of their participation in this study. The primary analysis team, led by the principal investigator, performs anonymous processing and data cleaning on all collected data. After the primary paper is published, among all chief investigators and collaborators at participating sites, those who wish to review the data from their own institution may access the data with the permission of the principal investigator or the research office. However, in order to conduct a sub-analysis using the data, they must submit the pre-specified application form for the sub-analysis to the Principal Investigator or the Research Office and receive their approval.

**(2) Authorship in the primary paper**

The primary paper’s author will include the Supervisor, the Principal Investigator, core research members, the Steering Committee members, regional leaders, and one representative from each participating site (should be the chief investigator). The order of co-authorship will be determined according to their contribution (e.g. the number of case enrolments, or the data entry rate). If there is a limitation on the number of co-authors, they will be included up to the limit according to their contribution, and the names of other collaborators will be listed as group authorship (in both cases their names will appear in PubMed). All other collaborators and co-investigators will be listed in the Appendix if they wish. To note, the chief investigators of the participating sites with fewer than three enrolled patients will have their names and affiliations listed in the Appendix. If one participating site enrols 15 and more patients (less than 20), they can add one more collaborator who will be provided with authorship, listed as group authorship. If one participating site enrols 20 patients (a maximum number for this study), a total of two additional collaborators can be listed as group authorship.

**(3) Apply for the sub-analysis**

The chief investigators of the participating sites may submit an application form for sub-analysis to the principal investigator or the research office at any time during the research period. The analysis team, led by the chief investigator who submit it, can conduct the analysis only if they receive the approval. If the application is approved, only the data will be provided to the chief investigators of the participating sites. In the case of a similar sub-analysis being submitted by several participating sites, the principal investigator and the research office will make a decision on who should analyze the data first based on the analysis topic, analysis schedule, number of case enrollments and data entry rate. If the submitted sub-analysis has not been submitted to a journal (regardless of acceptance) one year after the approval, the right to analyze the data will be transferred to another investigator who submitted a similar sub-analysis.

**(4) Authorship in the sub-analysis paper**

The chief investigators of the participating sites who have the responsibility for sub-analysis can define the Authorship. In general, the Supervisor and the Principal Investigator should always be included in the Authorship. Furthermore, one or two core research members of the LIBERATION Study who will help the participating sites until publication should be also included in the Authorship. The regional leader in charge of the participating site that conducts the sub-analysis should be given Authorship if the regional leader meets the criteria (recruitment of 10 sites, data input of 90% or more at the participating sites in charge). Even if the criteria are not met, at least group authorship will be given to the regional leader. In addition, non-assigned core research members, the Steering committee members, and other chief investigators at participating sites should be given the Authorship or Group Authorship according to the Journal Policy/Introductions. All other collaborators at participating sites will be listed in the Acknowledgement or Appendix if they wish. To note, the chief investigators of the participating sites with fewer than five enrolled patients will have their names and affiliations listed in the Acknowledgement or Appendix.

I understand and voluntarily agree to the above.

Date (Month/Day/Year)：　　　　　　　　　　　Signature