

# Confidentiality Agreement

This agreement is between:

Kensuke Nakamura, MD, PhD

Principal Investigators

LIBERATION Study Steering Committee

( hereinafter referred to as “Principal Investigator (PIs)” )

**and**

First Name:

Last Name:

Institution:

Department:

Address:

Country:

( hereinafter referred to as “Institution”)

**for**

ReLaTionship BEtween implementation of  
evidence-based and suppoRtive ICU cAre and  
ouTcomes of patIents with acute respiratOry distress syNdrome

~ LIBERATION Study ~

As a participating institution in the LIBERATION study,

Institution agrees to:

1. keep all the related research information shared with Institution confidential. Institution will not discuss or share the research information with anyone other than the relevant collaborators or others identified by PIs and the LIBERATION Study Steering Committee without appropriate permission.
2. keep all research information secure through reasonable efforts, no less than Institution's other Confidential Information of a similar nature while in Institution's possession. Institution through Investigator will follow the instructions of the PIs and the LIBERATION Study Steering Committee within the confines of applicable law and Institutional policy.
3. Confidential Information shall be marked or identified as "confidential" at the time of disclosure. Confidential Information disclosed orally shall be considered Confidential Information only if such information is confirmed in writing as being Confidential Information within thirty (30) days of the initial disclosure; provided, however, that information which is orally or visually disclosed, or written information that is not marked as "confidential," shall be considered confidential if it would be apparent to a reasonable person, familiar with the healthcare industry, that such information is of a confidential or proprietary nature.
4. on termination of this Agreement for any reason, PIs may request that the Institution return or destroy any Confidential Information obtained from the other party, provided, however, Institution may retain a copy of the other party's Confidential Information to (a) comply with applicable law, regulation, or internal compliance policies, (b) exercise its rights hereunder, or (c) determine its obligations hereunder. A party shall not be required to destroy electronic files created in the ordinary course of business during automatic system backup procedures so long as such electronic files are maintained only on centralized storage servers and are accessible only by any of its information technology specialists.
5. comply with the instructions and requests of PIs and the LIBERATION Study Steering Committee about requirements to physically and/or electronically secure records (including password protection, a correspondence table of individuals matching to study registration numbers, file/folder encryption, and/or use of secure electronic transfer of records through file sharing, use of online electrical data capture specifically developed for this project, use of virtual private networks, etc.) within the confines of applicable law and Institutional policy.
6. not allow any personally identifiable information to which Institution has access to be accessible from outside the country of the Institution (unless specifically instructed otherwise in writing by PIs and the LIBERATION Study Steering Committee and within the confines of applicable law).
7. remain this Agreement in effect for the entire study period that shall commence after being signed by PIs and the representative of the participating institution.
8. remain silent on the matter of governing law

Please sign, date and return a copy of this agreement to confirm your acceptance of its terms.

Accepted and agreed to: For and on behalf of

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(Print Name)

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(Signature)

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(Date)

As the PI in the LIBERATION study,

I agree to:

1. provide detailed directions and instructions on my expectations for maintaining the confidentiality of research information so that the participating institutions and the collaborating investigators can comply with the above terms.

Accepted and agreed to: For and on behalf of

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(Print Name)

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(Signature)

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(Date)

The plan for this study has been reviewed for its adherence to ethical guidelines and approved by the Research Ethics Board (Committee Number approved by Ministry of Health, Labour, and Welfare in Japan: 220000035) at the Japanese Society of Early Mobilization. For questions regarding participant rights and ethical conduct of research, contact the Research Ethics

Office at + 81-3-3556-5585.